In the depressed and anxious patient

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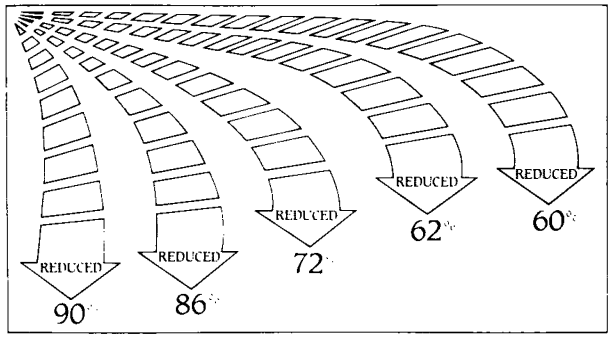
In The First Week...[1]
And The Weeks That Follow

74% of patients experienced improved sleep after the first *h.s.* dose[1]

First week reduction in somatic symptoms[1]

Percentage of Reduction in Individual Somatic Symptoms During First Week of Limbitrol Therapy*



*Patients often presented with more than one somatic symptom.

Limbitrol®

Each tablet contains 5 mg chlordiazepoxide and 12.5 mg amitriptyline (as the hydrochloride salt) Ⓒ Ⓘ Ⓥ

Limbitrol DS®

Each tablet contains 10 mg chlordiazepoxide and 25 mg amitriptyline (as the hydrochloride salt) Ⓒ Ⓘ Ⓥ

Caution patients about the combined effects of Limbitrol with alcohol or other CNS depressants and about activities requiring complete mental alertness, such as operating machinery or driving a car. In general, limit dosage to the lowest effective amount in elderly patients.

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Please see summary of product information on following page.

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***CAPOTEN® (captopril tablets) may be used as initial therapy only for patients with normal renal function in whom the risk of neutropenia/agranulocytosis is relatively low (1 out of over 8,600 in clinical trials). Use special precautions in patients with impaired renal function, collagen vascular disorders, or those exposed to other drugs known to affect the white cells or immune response. Evaluation of hypertensives should always include assessment of renal function. Overall, the most frequently occurring adverse reactions associated with CAPOTEN are skin rash and taste alteration; both effects are generally mild, reversible, or self-limited. See INDICATIONS AND USAGE, WARNINGS, and ADVERSE REACTIONS in the brief summary on the adjacent page.**

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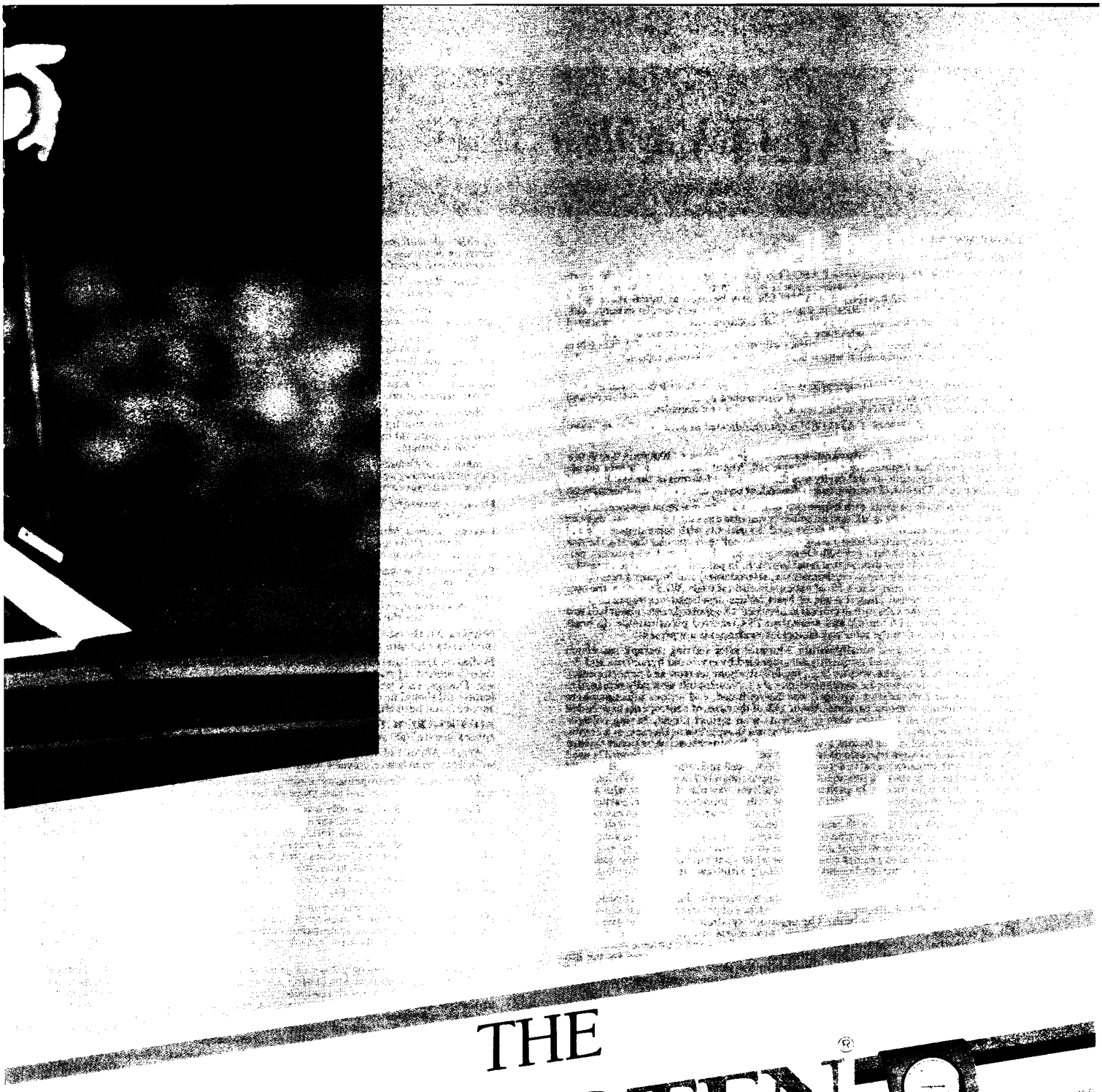
1. Croog SH, Levine S, Testa MA, et al: The effects of antihypertensive therapy on the quality of life. N Engl J Med 314(26):1657-1664, 1986.
2. Data on file, University of Connecticut.



THE CAPOTEN® (captopril tablets) DIFFERENCE

QUALITY OF LIFE THE CAPOTEN® (captopril tablets) DIFFERENCE

CAPOTEN* TABLETS

Captopril Tablets

INDICATIONS: Hypertension – CAPOTEN (captopril) is indicated for the treatment of hypertension. Consideration should be given to the risk of neutropenia/agranulocytosis (see WARNINGS). CAPOTEN may be used as initial therapy for patients with normal renal function, in whom the risk is relatively low. In patients with impaired renal function, particularly those with collagen vascular disease, captopril should be reserved for those who have either developed unacceptable side effects on other drugs, or have failed to respond satisfactorily to drug combinations. CAPOTEN is effective alone and in combination with other antihypertensive agents, especially thiazide-type diuretics.

Heart Failure: CAPOTEN (captopril) is indicated in patients with heart failure who have not responded adequately to or cannot be controlled by conventional diuretic and digitalis therapy. CAPOTEN is to be used with diuretics and digitalis.

CONTRAINDICATIONS: CAPOTEN is contraindicated in patients who are hypersensitive to this product.

WARNINGS: Neutropenia/Agranulocytosis – Neutropenia (1000/mm³) with myeloid hypoplasia has resulted from use of captopril. About half of the neutropenic patients developed systemic or oral cavity infections or other features of the syndrome of agranulocytosis. The risk of neutropenia is dependent on the clinical status of the patient:

In clinical trials in patients with hypertension who have normal renal function (serum creatinine less than 1.6 mg/dL and no collagen vascular disease), neutropenia has been seen in one patient out of over 8,600 exposed. In patients with some degree of renal failure (serum creatinine at least 1.6 mg/dL) but no collagen vascular disease, the risk in clinical trials was about 1 per 500. Doses were relatively high in these patients, particularly in view of their diminished renal function. In patients with collagen vascular diseases (e.g., systemic lupus erythematosus, scleroderma) and impaired renal function, neutropenia occurred in 3.7% of patients in clinical trials. While none of the over 750 patients in formal clinical trials of heart failure developed neutropenia, it has occurred during the subsequent clinical experience. Of reported cases, about half had serum creatinine ≥ 1.6 mg/dL and more than 75% received procainamide. In heart failure, it appears that the same risk factors for neutropenia are present.

Neutropenia has appeared usually within 3 months after starting therapy, associated with myeloid hypoplasia and frequently accompanied by erythroid hypoplasia and decreased numbers of megakaryocytes (e.g., hypoplastic bone marrow and pancytopenia); anemia and thrombocytopenia were sometimes seen. Neutrophils generally returned to normal in about 2 weeks after captopril was discontinued, and serious infections were limited to clinically complex patients. About 13% of the cases of neutropenia have ended fatally, but almost all fatalities were in patients with serious illness, having collagen vascular disease, renal failure, heart failure or immunosuppressant therapy, or a combination of these complicating factors. **Evaluation of the hypertensive or heart failure patient should always include assessment of renal function.** If captopril is used in patients with impaired renal function, white blood cell and differential counts should be evaluated prior to starting treatment and at approximately 2-week intervals for about 3 months, then periodically. In patients with collagen vascular disease or who are exposed to other drugs known to affect the white cells or immune response, particularly when there is impaired renal function, captopril should be used only after an assessment of benefit and risk, and then with caution. All patients treated with captopril should be told to report any signs of infection (e.g., sore throat, fever). If infection is suspected, perform white cell counts without delay. Since discontinuation of captopril and other drugs has generally led to prompt return of the white count to normal, upon confirmation of neutropenia (neutrophil count 1000/mm³) withdraw captopril and closely follow the patient's course.

Proteinuria: Total urinary proteins 1 g per day were seen in about 0.7% of patients on captopril. About 90% of affected patients had evidence of prior renal disease or received high doses (150 mg/day), or both. The nephrotic syndrome occurred in about one-fifth of proteinuric patients. In most cases, proteinuria subsided or cleared within 6 months whether or not captopril was continued. The BUN and creatinine were seldom altered in proteinuric patients. Since most cases of proteinuria occurred by the 8th month of therapy with captopril, patients with prior renal disease or those receiving captopril at doses 150 mg per day, should have urinary protein estimates (dip-stick on 1st morning urine) before therapy, and periodically thereafter.

Hypotension: Excessive hypotension was rarely seen in hypertensive patients but is a possibility in severely salt/volume-depleted persons such as those treated vigorously with diuretics (see PRECAUTIONS [Drug Interactions]). In heart failure, where the blood pressure was either normal or low, transient decreases in mean blood pressure 20% were recorded in about half of the patients. This transient hypotension may occur after any of the first several doses and is usually well tolerated, although rarely it has been associated with arrhythmia or conduction defects. A starting dose of 6.25 or 12.5 mg tid may minimize the hypotensive effect. Patients should be followed closely for the first 2 weeks of treatment and whenever the dose of captopril and/or diuretic is increased.

BECAUSE OF THE POTENTIAL FALL IN BLOOD PRESSURE IN THESE PATIENTS, THERAPY SHOULD BE STARTED UNDER VERY CLOSE MEDICAL SUPERVISION.

PRECAUTIONS: General: *Impaired Renal Function* – Hypertension – Some hypertensive patients with renal disease, particularly those with severe renal artery stenosis, have developed increases in BUN and serum creatinine. It may be necessary to reduce captopril dosage and/or discontinue diuretic. For some of these patients, normalization of blood pressure and maintenance of adequate renal perfusion may not be possible. Heart Failure – About 20% of patients develop stable elevations of BUN and serum creatinine 20% above normal or baseline upon long-term treatment. Less than 5% of patients, generally with severe preexisting renal disease, required discontinuation due to progressively increasing creatinine. See DOSAGE AND ADMINISTRATION, ADVERSE REACTIONS [Altered Laboratory Findings]. *Valvular Stenosis* – A theoretical concern, for risk of decreased coronary perfusion, has been noted regarding vasodilator treatment in patients with aortic stenosis due to decreased afterload reduction. *Surgery/Anesthesia* – If hypotension occurs during surgery or anesthesia, and is considered due to the effects of captopril, it is correctable by volume expansion.

Drug Interactions: *Hypotension – Patients on Diuretic Therapy* – Precipitous reduction of blood pressure may occasionally occur within the 1st hour after administration of the initial of captopril dose in patients on diuretics, especially those recently placed on diuretics, and those on severe dietary salt restriction or dialysis. This possibility can be minimized by either discontinuing the diuretic or increasing the salt intake about 1 week prior to initiation of captopril therapy or by initiating therapy with small doses (6.25 or 12.5 mg). Alternatively, provide medical supervision for at least 1 hour after the initial dose.

Agents Having Vasodilator Activity – In heart failure patients, vasodilators should be administered with caution.

Agents Causing Renin Release – Captopril's effect will be augmented by antihypertensive agents that cause renin release.

Agents Affecting Sympathetic Activity – The sympathetic nervous system may be especially important in supporting blood pressure in patients receiving captopril alone or with diuretics. Beta-adrenergic blocking drugs add some further antihypertensive effect to captopril, but the overall response is less than additive. Therefore, use agents affecting sympathetic activity (e.g., ganglionic blocking agents or adrenergic neuron blocking agents) with caution.

Agents Increasing Serum Potassium – Give potassium-sparing diuretics or potassium supplements only for documented hypokalemia, and then with caution, since they may lead to a significant increase of serum potassium. Use potassium-containing salt substitutes with caution.

Inhibitors of Endogenous Prostaglandin Synthesis – Indomethacin and other nonsteroidal anti-inflammatory agents may reduce the antihypertensive effect of captopril, especially in low renin hypertension.

Drug/Laboratory Test Interaction: Captopril may cause a false-positive urine test for acetone.

Carcinogenesis, Mutagenesis and Impairment of Fertility: Two-year studies with doses of 50 to 1350 mg/kg/day in mice and rats failed to show any evidence of carcinogenic potential. Studies in rats have revealed no impairment of fertility.

Pregnancy: Category C: There are no adequate and well-controlled studies in pregnant women. Embryocidal effects and craniofacial malformations were observed in rabbits. Therefore, captopril should be used during pregnancy, or for patients likely to become pregnant, only if the potential benefit outweighs the potential risk to the fetus. Captopril crosses the human placenta.

Nursing Mothers: Captopril is secreted in human milk. Exercise caution when administering captopril to a nursing woman, and, in general, nursing should be interrupted.

Pediatric Use: Safety and effectiveness in children have not been established although there is limited experience with use of captopril in children from 2 months to 15 years of age. Dosage, on a weight basis, was comparable to that used in adults. CAPOTEN (captopril) should be used in children only if other measures for controlling blood pressure have not been effective.

ADVERSE REACTIONS: Reported incidences are based on clinical trials involving approximately 7000 patients.

Renal – About 1 of 100 patients developed proteinuria (see WARNINGS). Renal insufficiency, renal failure, polyuria, oliguria, and urinary frequency in 1 to 2 of 1000 patients.

Hematologic – Neutropenia/agranulocytosis has occurred (see WARNINGS). Anemia, thrombocytopenia, and pancytopenia have been reported.

Dermatologic – Rash, (usually maculopapular, rarely urticarial), often with pruritus, and sometimes with fever and eosinophilia, in about 4 to 7 of 100 patients (depending on renal status and dose), usually during the 1st 4 weeks of therapy. Pruritus, without rash, in about 2 of 100 patients. A reversible associated pemphigoid-like lesion, and photosensitivity, have also been reported. Angioedema of the face, mucous membranes of the mouth, or of the extremities in about 1 of 1000 patients – reversible on discontinuance of captopril therapy. One case of laryngeal edema has been reported. Flushing or pallor in 2 to 5 of 1000 patients.

Cardiovascular – Hypotension may occur; see WARNINGS and PRECAUTIONS [Drug Interactions] for discussion of hypotension on initiation of captopril therapy. Tachycardia, chest pain, and palpitations each in about 1 of 100 patients. Angina pectoris, myocardial infarction, Raynaud's syndrome, and congestive heart failure each in 2 to 3 of 1000 patients.

Dysgeusia – Approximately 2 to 4 (depending on renal status and dose) of 100 patients developed a diminution or loss of taste perception; taste impairment is reversible and usually self-limited even with continued drug use (2 to 3 months). Gastric irritation, abdominal pain, nausea, vomiting, diarrhea, anorexia, constipation, aphthous ulcers, peptic ulcer, dizziness, headache, malaise, fatigue, insomnia, dry mouth, dyspnea, cough, alopecia, paresthesias reported in about 0.5 to 2% of patients but did not appear at increased frequency compared to placebo or other treatments used in controlled trials.

Altered Laboratory Findings: Elevations of liver enzymes in a few patients although no causal relationship has been established. Rarely cholestatic jaundice, and hepatocellular injury with or without secondary cholestasis, have been reported. A transient elevation of BUN and serum creatinine may occur, especially in volume-depleted or renovascular hypertension patients. In instances of rapid reduction of longstanding or severely elevated blood pressure, the glomerular filtration rate may decrease transiently, also resulting in transient rises in serum creatinine and BUN. Small increases in serum potassium concentration frequently occur, especially in patients with renal impairment (see PRECAUTIONS).

OVERDOSAGE: Primary concern is correction of hypotension. Volume expansion with an I.V. infusion of normal saline is the treatment of choice for restoration of blood pressure. Captopril may be removed from the general circulation by hemodialysis.

DOSAGE AND ADMINISTRATION: CAPOTEN (captopril) should be taken one hour before meals. In hypertension, CAPOTEN may be dosed bid or tid. Dosage must be individualized; see DOSAGE AND ADMINISTRATION section of package insert for detailed information regarding dosage in hypertension and in heart failure. Because CAPOTEN (captopril) is excreted primarily by the kidneys, dosage adjustments are recommended for patients with impaired renal function.

Consult package insert before prescribing CAPOTEN (captopril).

HOW SUPPLIED: Available in tablets of 12.5, 25, 50, and 100 mg in bottles of 100 (25 mg and 50 mg also available in bottles of 1000), and in UNIMATIC® unit-dose packs of 100 tablets. (J3-658J)

SQUIBB®

528-506 Issued: January 1988

ARMY RESERVE MEDICAL PROFILE NO. 4

ROBERT CHEONG LIM, J.R., M.D.

Professor of Surgery, University of California School of Medicine, San Francisco, California

Chief, Vascular Surgery Service, San Francisco General Hospital

Consultant, Letterman Army Medical Center

Colonel, U.S. Army Reserve

EDUCATION University of California at Berkeley, A.B.; University of California School of Medicine, San Francisco, M.D.

RESIDENCY University of California School of Medicine.

FELLOWSHIPS NIH Fellowship in Vascular Surgery, V.A. Hospital, San Francisco; National Heart Institute Special Fellowship in Thromboembolic Diseases and Microcirculation, University of Gothenburg, Sweden.

OUTSTANDING ACHIEVEMENTS Joe Shoong Fellowship; Earl Hamilton Cornell Scholarship in Medicine; Ligature Order (Sweden); Alpha Omega Alpha; Distinguished Service Award, Youth Opportunity Program, HEW; Special Consultant, Special Project Office on Emergency Medical Services, HEW; Chinese-American Physicians Society; Who's Who in America.

"My professional career is devoted to patient care, teaching and research. Because of my special interest in the field of trauma surgery, I feel especially close to the work being done at Army medical centers such as Letterman Army Medical Center in San Francisco. I am particularly impressed with what they are doing to prepare young Army surgeons in dealing with trauma injuries.

"I joined the Army Reserve because I personally wanted to become more involved with military medicine at Letterman. It has a superior training program, and the quality of military medicine practiced is outstanding. The excellent care patients receive at Army medical facilities is up-to-date and surpasses the standard of care in many means. By being part of that team, I can provide the necessary backup, if needed, in a national emergency.

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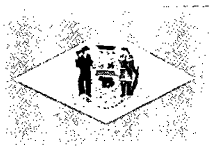

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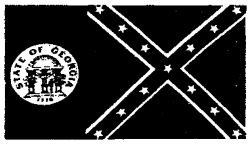

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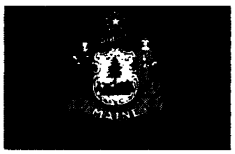

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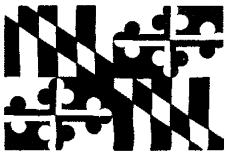

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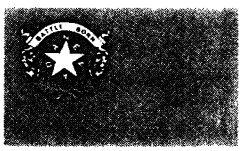

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Compatible with other antianginals[6†]

Safe in angina with coexisting hypertension, COPD, asthma, or PVD[1,3,5,6]

**CARDIZEM® (diltiazem HCl) is indicated in the treatment of angina pectoris due to coronary artery spasm and in the management of chronic stable angina (classic effort-associated angina) in patients who cannot tolerate therapy with beta-blockers and/or nitrates or who remain symptomatic despite adequate doses of these agents.*

†See Warnings and Precautions.

Please see brief summary of prescribing information on the next page.

1419H8

CARDIZEM® ANTIANGINAL PROTECTION PLUS SAFETY

diltiazem HCl/Marion

Usual maintenance dosage range: 180-360 mg/day

CARDIZEM®
(diltiazem HCl)
30 mg, 60 mg, 90 mg and 120 mg Tablets

CONTRAINDICATIONS

CARDIZEM is contraindicated in (1) patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker, (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker, (3) patients with hypotension (less than 90 mm Hg systolic), (4) patients who have demonstrated hypersensitivity to the drug, and (5) patients with acute myocardial infarction and pulmonary congestion documented by x-ray on admission.

WARNINGS

1. **Cardiac Conduction.** CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time, except in patients with sick sinus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1,243 patients for 0.48%). Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. A patient with Prinzmetal's angina developed periods of asystole (2 to 5 seconds) after a single dose of 60 mg of diltiazem.
2. **Congestive Heart Failure.** Although diltiazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (dp/dt). Experience with the use of CARDIZEM alone or in combination with beta-blockers in patients with impaired ventricular function is very limited. Caution should be exercised when using the drug in such patients.
3. **Hypotension.** Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic hypotension.
4. **Acute Hepatic Injury.** In rare instances, significant elevations in enzymes such as alkaline phosphatase, LDH, SGOT, SGPT, and other phenomena consistent with acute hepatic injury have been noted. These reactions have been reversible upon discontinuation of drug therapy. The relationship to CARDIZEM is uncertain in most cases, but probable in some. (See PRECAUTIONS.)

PRECAUTIONS

General. CARDIZEM (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and in bile. As with any drug given over prolonged periods, laboratory parameters should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic function. In subacute and chronic dog and rat studies designed to produce toxicity, high doses of diltiazem were associated with hepatic damage. In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/kg were also associated with hepatic changes; however, these changes were reversible with continued dosing.

Dermatological events (see ADVERSE REACTIONS section) may be transient and may disappear despite continued use of CARDIZEM. However, skin eruptions progressing to erythema multiforme and/or exfoliative dermatitis have also been infrequently reported. Should a dermatologic reaction persist, the drug should be discontinued.

Drug Interaction. Due to the potential for additive effects, caution and careful titration are warranted in patients receiving CARDIZEM concomitantly with any agents known to affect cardiac contractility and/or conduction. (See WARNINGS.)

Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or digitalis concomitantly with CARDIZEM. (See WARNINGS.)

As with all drugs, care should be exercised when treating patients with multiple medications. CARDIZEM undergoes biotransformation by cytochrome P-450 mixed function oxidase. Coadministration of CARDIZEM with other agents which follow the same route of biotransformation may result in the competitive inhibition of metabolism. Dosages of similarly metabolized drugs, particularly those of low therapeutic ratio or in patients with renal and/or hepatic impairment, may require adjustment when starting or stopping concomitantly administered CARDIZEM to maintain optimum therapeutic blood levels.

Beta-blockers: Controlled and uncontrolled domestic studies suggest that concomitant use of CARDIZEM and beta-blockers or digitalis is usually well tolerated. Available data are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities.

Administration of CARDIZEM (diltiazem hydrochloride) concomitantly with propranolol in five normal volunteers resulted in increased propranolol levels in all subjects and bioavailability of propranolol was increased approximately 50%. If combination therapy is initiated or withdrawn in conjunction with propranolol, an adjustment in the propranolol dose may be warranted. (See WARNINGS.)

Cimetidine: A study in six healthy volunteers has shown a significant increase in peak diltiazem plasma levels (58%) and area-under-the-curve (53%) after a one-week course of cimetidine at 1,200 mg per day and diltiazem 60 mg per day. Ranitidine produced smaller, nonsignificant increases. The effect may be mediated by cimetidine's known inhibition of hepatic cytochrome P-450, the enzyme system probably responsible for the first-pass metabolism of diltiazem. Patients currently receiving diltiazem therapy should be carefully monitored for a change in pharmacological effect when initiating and discontinuing therapy with cimetidine. An adjustment in the diltiazem dose may be warranted.

Digitalis: Administration of CARDIZEM with digoxin in 24 healthy male subjects increased plasma digoxin concentrations approximately 20%. Another investigator found no increase in digoxin levels in 12 patients with coronary artery disease. Since there have been conflicting results regarding the effect of digoxin levels, it is recommended that digoxin levels be monitored when initiating, adjusting, and discontinuing CARDIZEM therapy to avoid possible over- or under-digitalization. (See WARNINGS.)

Anesthetics: The depression of cardiac contractility, conductivity, and automaticity as well as the vascular dilation associated with anesthetics may be potentiated by calcium channel blockers. When used concomitantly, anesthetics and calcium blockers should be titrated carefully.

Carcinogenesis, Mutagenesis, Impairment of Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity. There was also no mutagenic response in in vitro bacterial tests. No intrinsic effect on fertility was observed in rats.

Pregnancy. Category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryo and fetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stillbirths at doses of 20 times the human dose or greater.

There are no well-controlled studies in pregnant women; therefore, use CARDIZEM in pregnant women only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. Diltiazem is excreted in human milk. One report suggests that concentrations in breast milk may approximate serum levels. If use of CARDIZEM is deemed essential, an alternative method of infant feeding should be instituted.

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded.

Rx

Cardizem® (diltiazem HCl)

☐ 60 mg ☐ 90 mg

☐ 120 mg

Sig: tid

In domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that reported during placebo therapy.

The following represent occurrences observed in clinical studies which can be at least reasonably associated with the pharmacology of calcium influx inhibition. In many cases, the relationship to CARDIZEM has not been established. The most common occurrences as well as their frequency of presentation are: edema (2.4%), headache (2.1%), nausea (1.9%), dizziness (1.5%), rash (1.3%), asthenia (1.2%). In addition, the following events were reported infrequently (less than 1%):

Cardiovascular:	Angina, arrhythmia, AV block (first degree), AV block (second or third degree—see conduction warning), bradycardia, congestive heart failure, flushing, hypotension, palpitations, syncope.
Nervous System:	Amnesia, depression, gait abnormality, hallucinations, insomnia, nervousness, paresthesia, personality change, somnolence, tinnitus, tremor.
Gastrointestinal:	Anorexia, constipation, diarrhea, dysgeusia, dyspepsia, mild elevations of alkaline phosphatase, SGOT, SGPT, and LDH (see hepatic warnings), vomiting, weight increase.
Dermatologic:	Petechiae, pruritus, photosensitivity, urticaria.
Other:	Amblyopia, CPK elevation, dyspnea, epistaxis, eye irritation, hyperglycemia, nasal congestion, nocturia, osteoarticular pain, polyuria, sexual difficulties.

The following postmarketing events have been reported infrequently in patients receiving CARDIZEM: alopecia, gingival hyperplasia, erythema multiforme, and leukopenia. However, a definitive cause and effect between these events and CARDIZEM therapy is yet to be established.

Issued 3/1/88

See complete Professional Use Information before prescribing.

References: 1. Schroeder JS: Mod Med 1982;50(Sept):94-116. **2.** Cohn PF, Braunwald E: Chronic ischemic heart disease, in Braunwald E (ed): Heart Disease: A Textbook of Cardiovascular Medicine, ed 2. Philadelphia, WB Saunders Co, 1984, chap 39. **3.** O'Rourke RA: Am J Cardiol 1985;56:34H-40H. **4.** McCall D, Walsh RA, Frohlich ED, et al: Curr Probl Cardiol 1985;10(8):6-80. **5.** Frishman WH, Charlap S, Goldberger J, et al: Am J Cardiol 1985;56:41H-46H. **6.** Shapiro W: Consultant 1984;24(Dec):150-159. **7.** O'Hara MJ, Khurmi NS, Bowles MJ, et al: Am J Cardiol 1984;54:477-481. **8.** Strauss WE, McIntyre KM, Parisi AF, et al: Am J Cardiol 1982; 49:560-566. **9.** Feldman RL, Pepine CJ, Whittle J, et al: Am J Cardiol 1982;49:554-559.

1419H8

Her anxiolytic is working—but she's alert, functioning, and at no risk of a benzodiazepine withdrawal syndrome when therapy ends.

That's

Efficacy!

BuSpar relieves anxiety and returns your patient to normal activity

...with no more sedation than induced by placebo[1]
...without impairing psychomotor function in most patients*[2]
...without producing a benzodiazepine withdrawal syndrome[3] upon discontinuation

The first choice for chronic anxiety

BuSpar®

Tablets, 5 mg and 10 mg

(buspirone HCl)

for a different kind of calm

*Because the effects of BuSpar in any individual patient may not be predictable, patients should be cautioned about operating an automobile or using complex machinery until they are reasonably certain that BuSpar treatment does not affect them adversely.

For Brief Summary, please see following page.

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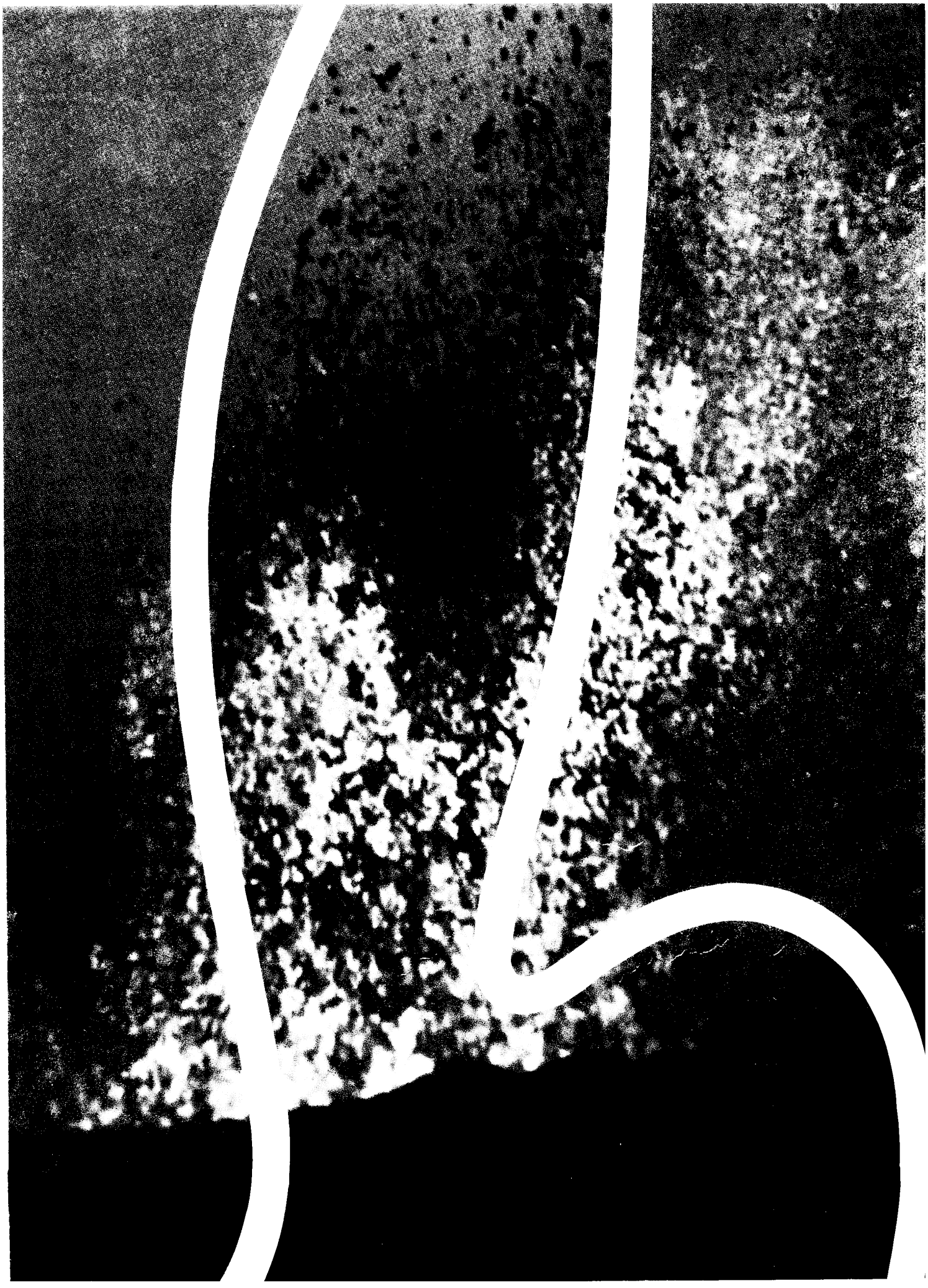


The only H_2-antagonist indicated for the treatment of gastroesophageal reflux disease

WHEN ACID REFLUX ERUPTS

Zantac dramatically lessens pain of acid reflux[1] by inhibiting the formation of acid at its source—an action unique among pharmaceutical agents indicated for the treatment of gastroesophageal reflux disease.

Zantac® *Tablets*

ranitidine HCl/Glaxo

150 mg tablets bid

1. Sontag S, Robinson M, McCallum RW, et al: Ranitidine therapy for gastroesophageal reflux disease. Results of a large double-blind trial. *Arch Intern Med* 1987;147:1485-1491.

Please see next page for Brief Summary of Prescribing Information.

Glaxo / ROCHE

The World's Most Popular K*

Slow-K®

potassium chloride
slow-release tablets
8 mEq (600 mg)

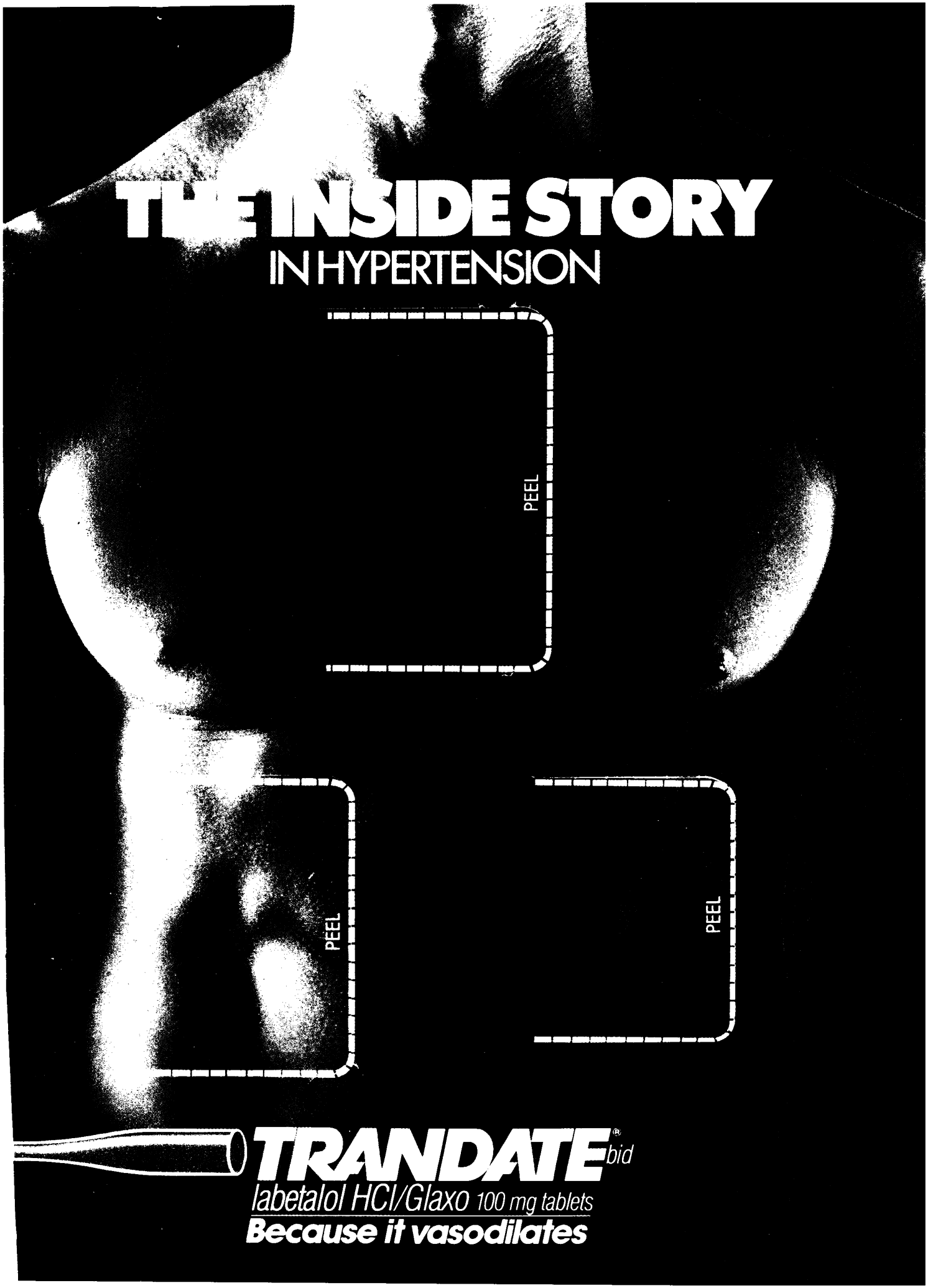
It means "dependability" in almost any language

*Based on worldwide sales data on file, CIBA Pharmaceutical Company.
Capsule or tablet slow-release potassium chloride preparations should be reserved for patients who cannot tolerate, refuse to take, or have compliance problems with liquid or effervescent potassium preparations because of reports of intestinal and gastric ulceration and bleeding with slow-release KCl preparations.

Before prescribing, please consult Brief Prescribing Information on next page.

CIBA

128-3568-A


THE INSIDE STORY
IN HYPERTENSION
PEEL
PEEL
PEEL
TRANDATE® bid
labetalol HCl/Glaxo 100 mg tablets
Because it vasodilates


SIDE STORY
OMISED VITALITY
Low incidence of
fatigue and impotence[7]
Preserves exercise
tolerance
Improved quality of
patient daily existence
Transdate Tablets are
failure, greater-than-
severe bradycardia.
For references and co
including incidence
REACTIONS section
effective blood pressure control
TRANDATE® bid
labetalol HCl/Glaxo 100 mg tablets
because it vasodilates

References: 1. Malini PL, Strocchi E, Negroni S, et al: Renal haemodynamics after chronic treatment with labetalol and propranolol. *Br J Clin Pharmacol* 1982;13(suppl 1):123S-126S. **2.** Pedersen EB, Larsen JS: Effect of propranolol and labetalol on renal haemodynamics at rest and during exercise in essential hypertension. *Postgrad Med J* 1980;56(suppl 2):27-32. **3.** Wallin JD: Antihypertensives and their impact on renal function. *Am J Med* 1983;75:103-108. **4.** Koch G: Haemodynamic adaptation at rest and during exercise to long-term antihypertensive treatment with combined alpha- and beta-adrenoreceptor blockade by labetalol. *Br Heart J* 1979;41(2):192-198. **5.** Feit A, Holtzman R, Cohen M, et al: Effect of labetalol on exercise tolerance and double product in mild to moderate essential hypertension. *Am J Med* 1985;78:937-941. **6.** Lund-Johansen P: Short- and long-term (six-year) hemodynamic effects of labetalol in essential hypertension. *Am J Med* 1983;75:24-31. **7.** Burris JF, Goldstein J, Zager PG, et al: Comparative tolerability of labetalol versus propranolol, atenolol, pindolol, metoprolol, and nadolol. *J Clin Hypertens* 1986;3:285-293.

TRANDATE® Tablets
(labetalol hydrochloride)

BRIEF SUMMARY

The following is a brief summary only. Before prescribing, see complete prescribing information in TRANDATE® Tablets product labeling.

CONTRAINDICATIONS: TRANDATE® Tablets are contraindicated in bronchial asthma, overt cardiac failure, greater-than-first-degree heart block, cardiogenic shock, and severe bradycardia (see WARNINGS).

WARNINGS: Cardiac Failure: Sympathetic stimulation is a vital component supporting circulatory function in congestive heart failure. Beta-blockade carries a potential hazard of further depressing myocardial contractility and precipitating more severe failure. Although beta-blockers should be avoided in overt congestive heart failure, if necessary, labetalol HCl can be used with caution in patients with a history of heart failure who are well compensated. Congestive heart failure has been observed in patients receiving labetalol HCl. Labetalol HCl does not abolish the inotropic action of digitalis on heart muscle.

In Patients Without a History of Cardiac Failure: In patients with latent cardiac insufficiency, continued depression of the myocardium with beta-blocking agents over a period of time can, in some cases, lead to cardiac failure. At the first sign or symptom of impending cardiac failure, patients should be fully digitalized and/or be given a diuretic, and the response should be observed closely. If cardiac failure continues despite adequate digitalization and diuretic, TRANDATE® therapy should be withdrawn (gradually, if possible).

Exacerbation of Ischemic Heart Disease Following Abrupt Withdrawal: Angina pectoris has not been reported upon labetalol HCl discontinuation. However, hypersensitivity to catecholamines has been observed in patients withdrawn from beta-blocker therapy; exacerbation of angina and, in some cases, myocardial infarction have occurred after *abrupt* discontinuation of such therapy. When discontinuing chronically administered TRANDATE, particularly in patients with ischemic heart disease, the dosage should be gradually reduced over a period of one to two weeks and the patient should be carefully monitored. If angina markedly worsens or acute coronary insufficiency develops, TRANDATE administration should be reinstituted promptly, at least temporarily, and other measures appropriate for the management of unstable angina should be taken. Patients should be warned against interruption or discontinuation of therapy without the physician's advice. Because coronary artery disease is common and may be unrecognized, it may be prudent not to discontinue TRANDATE therapy abruptly even in patients treated only for hypertension.

Nonallergic Bronchospasm (eg, Chronic Bronchitis and Emphysema): Patients with bronchospastic disease should, in general, not receive beta-blockers. TRANDATE may be used with caution, however, in patients who do not respond to, or cannot tolerate, other antihypertensive agents. It is prudent, if TRANDATE is used, to use the smallest effective dose, so that inhibition of endogenous or exogenous beta-agonists is minimized.

Pheochromocytoma: Labetalol HCl has been shown to be effective in lowering blood pressure and relieving symptoms in patients with pheochromocytoma. However, paradoxical hypertensive responses have been reported in a few patients with this tumor; therefore, use caution when administering labetalol HCl to patients with pheochromocytoma.

Diabetes Mellitus and Hypoglycemia: Beta-adrenergic blockade may prevent the appearance of premonitory signs and symptoms (eg, tachycardia) of acute hypoglycemia. This is especially important with labile diabetics. Beta-blockade also reduces the release of insulin in response to hyperglycemia; it may therefore be necessary to adjust the dose of antidiabetic drugs.

Major Surgery: The necessity or desirability of withdrawing beta-blocking therapy before major surgery is controversial. Protracted severe hypotension and difficulty in restarting or maintaining a heartbeat have been reported with beta-blockers. The effect of labetalol HCl's alpha-adrenergic activity has not been evaluated in this setting.

A synergism between labetalol HCl and halothane anesthesia has been shown (see PRECAUTIONS: Drug Interactions).

PRECAUTIONS: General: *Impaired Hepatic Function:* TRANDATE® Tablets should be used with caution in patients with impaired hepatic function since metabolism of the drug may be diminished.

Jaundice or Hepatic Dysfunction: On rare occasions, labetalol HCl has been associated with jaundice (both hepatic and cholestatic). It is therefore recommended that treatment with labetalol HCl be stopped immediately should a patient develop jaundice or laboratory evidence of liver injury. Both have been shown to be reversible on stopping therapy.

Information for Patients: As with all drugs with beta-blocking activity, certain advice to patients being treated with labetalol HCl is warranted. This information is intended to aid in the safe and effective use of this medication. It is not a disclosure of all possible adverse or intended effects. While no incidence of the abrupt withdrawal phenomenon (exacerbation of angina pectoris) has been reported with labetalol HCl, dosing with TRANDATE Tablets should not be interrupted or discontinued without a physician's advice. Patients being treated with TRANDATE Tablets should consult a physician at any sign of impending cardiac failure. Also, transient scalp tingling may occur, usually when treatment with TRANDATE Tablets is initiated (see ADVERSE REACTIONS).

Laboratory Tests: As with any new drug given over prolonged periods, laboratory parameters should be observed over regular intervals. In patients with concomitant illnesses, such as impaired renal function, appropriate tests should be done to monitor these conditions.

Drug Interactions: In one survey, 2.3% of patients taking labetalol HCl in combination with tricyclic antidepressants experienced tremor as compared to 0.7% reported to occur with labetalol HCl alone. The contribution of each of the treatments to this adverse reaction is unknown, but the possibility of a drug interaction cannot be excluded.

Drugs possessing beta-blocking properties can blunt the bronchodilator effect of beta-receptor agonist drugs in patients with bronchospasm; therefore, doses greater than the normal antiasthmatic dose of beta-agonist bronchodilator drugs may be required.

Cimetidine has been shown to increase the bioavailability of labetalol HCl. Since this could be explained either by enhanced absorption or by an alteration of hepatic metabolism of labetalol HCl, special care should be used in establishing the dose required for blood pressure control in such patients.

Synergism has been shown between halothane anesthesia and intravenously administered labetalol HCl. During controlled hypotensive anesthesia using labetalol HCl in association with halothane, high concentrations (3% or above) of halothane should not be used because the degree of hypotension will

TRANDATE® Tablets (labetalol hydrochloride)

be increased and because of the possibility of a large reduction in cardiac output and an increase in central venous pressure. The anesthesiologist should be informed when a patient is receiving labetalol HCl.

Labetalol HCl blunts the reflex tachycardia produced by nitroglycerin without preventing its hypotensive effect. If labetalol HCl is used with nitroglycerin in patients with angina pectoris, additional antihypertensive effects may occur.

Drug/Laboratory Test Interactions: The presence of a metabolite of labetalol in the urine may result in falsely increased levels of urinary catecholamines when measured by a nonspecific trihydroxyindole (THI) reaction. In screening patients suspected of having a pheochromocytoma and being treated with labetalol HCl, specific radioenzymatic or high performance liquid chromatography assay techniques should be used to determine levels of catecholamines or their metabolites.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term oral dosing studies with labetalol HCl for 18 months in mice and for two years in rats showed no evidence of carcinogenesis. Studies with labetalol HCl using dominant lethal assays in rats and mice and exposing microorganisms according to modified Ames tests showed no evidence of mutagenesis.

Pregnancy: *Teratogenic Effects: Pregnancy Category C:* Teratogenic studies were performed with labetalol in rats and rabbits at oral doses up to approximately six and four times the maximum recommended human dose (MRHD), respectively. No reproducible evidence of fetal malformations was observed. Increased fetal resorptions were seen in both species at doses approximating the MRHD. A teratology study performed with labetalol in rabbits at intravenous doses up to 1.7 times the MRHD revealed no evidence of drug-related harm to the fetus. There are no adequate and well-controlled studies in pregnant women. Labetalol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects: Infants of mothers who were treated with labetalol HCl during pregnancy did not appear to be adversely affected by the drug. Oral administration of labetalol to rats during late gestation through weaning at doses of two to four times the MRHD caused a decrease in neonatal survival.

Labor and Delivery: Labetalol HCl given to pregnant women with hypertension did not appear to affect the usual course of labor and delivery.

Nursing Mothers: Small amounts of labetalol (approximately 0.004% of the maternal dose) are excreted in human milk. Caution should be exercised when TRANDATE Tablets are administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: Most adverse effects are mild, transient, and occur early in the course of treatment. In controlled clinical trials of three to four months' duration, discontinuation of TRANDATE® Tablets due to one or more adverse effects was required in 7% of all patients. In these same trials, beta-blocker control agents led to discontinuation in 8% to 10% of patients, and a centrally acting alpha-agonist in 30% of patients.

The following adverse reactions were derived from multicenter, controlled clinical trials over treatment periods of three and four months. The rates, which ranged from less than 1% to 5% except as otherwise noted, are based on adverse reactions considered probably drug-related by the investigator. If all reports are considered, the rates are somewhat higher (eg, dizziness, 20%; nausea, 14%; fatigue, 11%).

Body as a Whole: Fatigue, asthenia, headache. ***Gastrointestinal:*** Nausea (6%), vomiting, dyspepsia, diarrhea, taste distortion. ***Central and Peripheral Nervous Systems:*** Dizziness (11%), paresthesia, drowsiness. ***Autonomic Nervous System:*** Nasal stuffiness, ejaculation failure, impotence, increased sweating. ***Cardiovascular:*** Edema, postural hypotension. ***Respiratory:*** Dyspnea. ***Skin:*** Rash. ***Special Senses:*** Vision abnormality, vertigo.

The adverse effects were reported spontaneously and are representative of the incidence of adverse effects that may be observed in a properly selected hypertensive patient population, ie, a group excluding patients with bronchospastic disease, overt congestive heart failure, or other contraindications to beta-blocker therapy.

Clinical trials also included studies utilizing daily doses up to 2,400 mg in more severely hypertensive patients. The US therapeutic trials data base for adverse reactions that are clearly or possibly dose-related shows that the following side effects increased with increasing dose: dizziness, fatigue, nausea, vomiting, dyspepsia, paresthesia, nasal stuffiness, ejaculation failure, impotence, and edema.

In addition, a number of other less common adverse events have been reported in clinical trials or the literature:

Cardiovascular: Postural hypotension, including, rarely, syncope. ***Central and Peripheral Nervous Systems:*** Paresthesia, most frequently described as scalp tingling. In most cases, it was mild, transient, and usually occurred at the beginning of treatment. ***Collagen Disorders:*** Systemic lupus erythematosus; positive antinuclear factor (ANF). ***Eyes:*** Dry eyes. ***Immunological System:*** Antimitochondrial antibodies. ***Liver and Biliary System:*** Cholestasis with or without jaundice. ***Musculoskeletal System:*** Muscle cramps, toxic myopathy. ***Respiratory System:*** Bronchospasm. ***Skin and Appendages:*** Rashes of various types, such as generalized maculopapular, lichenoid, urticarial, bullous lichen planus, psoriaform, and facial erythema; Peyronie's disease; reversible alopecia. ***Urinary System:*** Difficulty in micturition, including acute urinary bladder retention.

Following approval for marketing in the United Kingdom, a monitored release survey involving approximately 6,800 patients was conducted for further safety and efficacy evaluation of this product. Results of this survey indicate that the type, severity, and incidence of adverse effects were comparable to those cited above.

Potential Adverse Effects: In addition, other adverse effects not listed above have been reported with other beta-adrenergic blocking agents. ***Central Nervous System:*** Reversible mental depression progressing to catatonia, an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on psychometrics. ***Cardiovascular:*** Intensification of AV block (see CONTRAINDICATIONS). ***Allergic:*** Fever combined with aching and sore throat; laryngospasm, respiratory distress. ***Hematologic:*** Agranulocytosis, thrombocytopenic or nonthrombocytopenic purpura. ***Gastrointestinal:*** Mesenteric artery thrombosis, ischemic colitis. The oculomucocutaneous syndrome associated with the beta-blocker practolol has not been reported with labetalol HCl.

Clinical Laboratory Tests: There have been reversible increases of serum transaminases in 4% of patients treated with labetalol HCl and tested, and more rarely, reversible increases in blood urea.

OVERDOSAGE: Information concerning possible overdosage and its treatment appears in the full prescribing information.

DOSAGE AND ADMINISTRATION: DOSAGE MUST BE INDIVIDUALIZED. The recommended *initial* dosage is 100 mg *twice* daily whether used alone or added to a diuretic regimen. After two or three days, using standing blood pressure as an indicator, dosage may be titrated in increments of 100 mg bid every two or three days. The usual *maintenance* dosage of labetalol HCl is between 200 and 400 mg *twice* daily. Before use, see complete prescribing information for dosage details.

April 1988

Glaxo

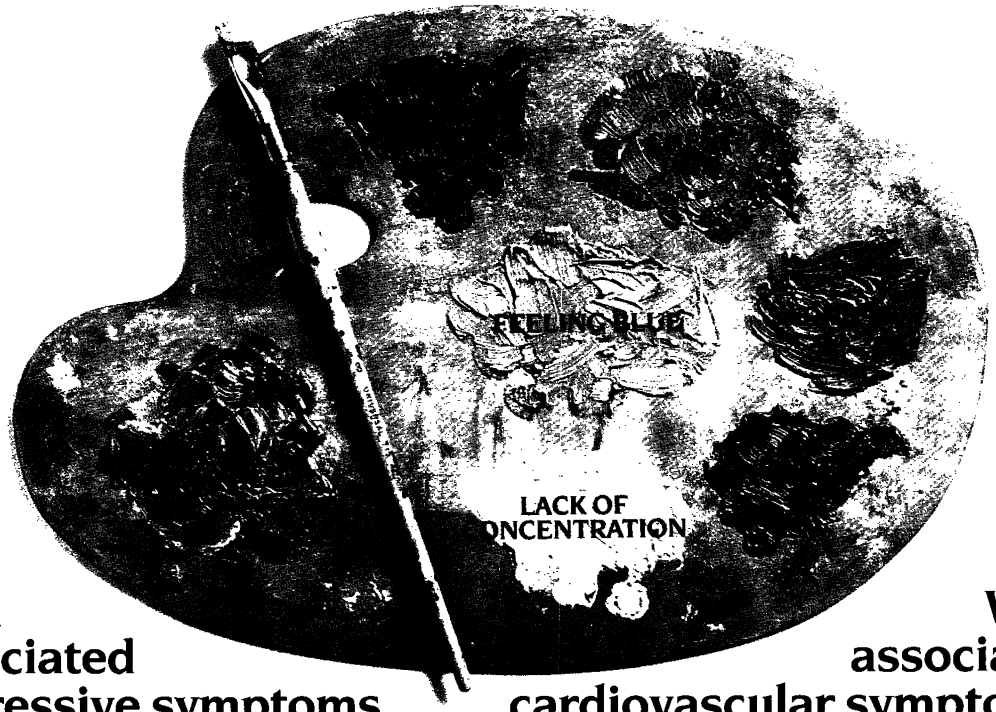
Glaxo Inc., Research Triangle Park, NC 27709

The portrait of anxiety

Upjohn The Upjohn Company
Kalamazoo, Michigan 49001 USA

Please see adjacent page for brief summary of prescribing information.

is often complicated



With associated depressive symptoms.

In double-blind, four-week clinical trials in 632 patients with moderate to severe anxiety, therapy with XANAX was compared with placebo.

XANAX was significantly more effective ($P<.001$) than placebo in relieving the anxiety, with over half of the patients showing marked to moderate improvement by the first evaluation period (one week).

In addition, over 70% of these patients experienced associated moderate to severe depressed mood. XANAX was shown to be significantly more effective ($P<.014$) than placebo in improving the associated depressed mood.

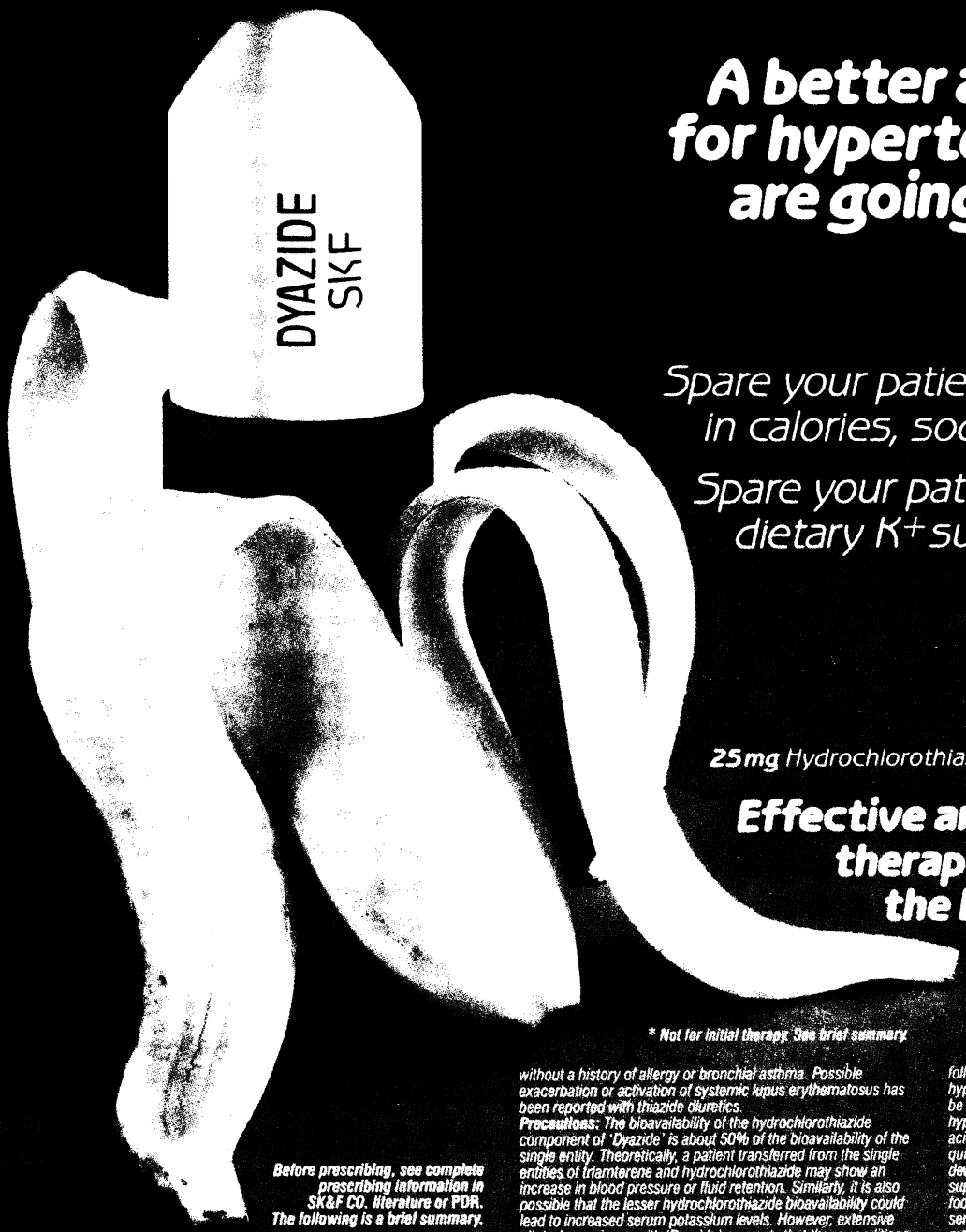
With associated cardiovascular symptoms.

Almost 60% of patients in the study had anxiety with associated cardiovascular symptoms even though cardiovascular disease had been ruled out. XANAX was shown to effectively relieve anxiety including the associated cardiovascular symptoms.

XANAX, the first of a unique class—the triazolobenzodiazepines.

- *Well tolerated*—Side effects, if they occur are generally observed at the beginning of therapy and usually disappear with continued medication. Drowsiness and light-headedness were the most commonly reported adverse reactions.
- *Sustained efficacy*—No reported increase in dosage during 16-week clinical study once an appropriate dosage was achieved. Since long-term effectiveness of XANAX has not been established, it is recommended that it not be used for longer than 16 weeks.
- *Simple dosage*—0.25 to 0.5 mg t.i.d.

for the relief of complicated anxiety



A better alternative for hypertensives who are going bananas...

Spare your patients the extra cost—in calories, sodium and dollars.

Spare your patients the rigors of dietary K^+ supplementation.

®

25 mg *Hydrochlorothiazide/***50 mg** *Triamterene/SKF*

Effective antihypertensive* therapy...without the bananas

DAW
'DYAZIDE' AS WRITTEN.

* Not for initial therapy. See brief summary.

Before prescribing, see complete prescribing information in SK&F CO. literature or PDR. The following is a brief summary.

* **WARNING**

This drug is not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual. If this combination represents the dosage so determined, its use may be more convenient in patient management. Treatment of hypertension and edema is not static, but must be reevaluated as conditions in each patient warrant.

Contraindications: *Concomitant use with other potassium-sparing agents such as spironolactone or amiloride. Further use in anuria, progressive renal or hepatic dysfunction, hyperkalemia. Pre-existing elevated serum potassium. Hypersensitivity to either component or other sulfonamide-derived drugs.*

Warnings:* Do not use potassium supplements, dietary or otherwise, unless hypokalemia develops or dietary intake of potassium is markedly impaired.** *If supplementary potassium is needed, potassium tablets should not be used. Hyperkalemia can occur, and has been associated with cardiac irregularities. It is more likely in the severely ill, with urine volume less than one liter/day, the elderly and diabetics with suspected or confirmed renal insufficiency. Periodically, serum K^+ levels should be determined. If hyperkalemia develops, substitute a thiazide alone, restrict K^+ intake.* ***Associated widened QRS complex or arrhythmia requires prompt additional therapy. *Thiazides cross the placental barrier and appear in cord blood. Use in pregnancy requires weighing anticipated benefits against possible hazards, including fetal or neonatal jaundice, thrombocytopenia, other adverse reactions seen in adults. Thiazides appear and triamterene may appear in breast milk. If their use is essential, the patient should stop nursing. Adequate information on use in children is not available. Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma. Possible exacerbation or activation of systemic lupus erythematosus has been reported with thiazide diuretics.*

Precautions: *The bioavailability of the hydrochlorothiazide component of 'Dyazide' is about 50% of the bioavailability of the single entity. Theoretically, a patient transferred from the single entities of triamterene and hydrochlorothiazide may show an increase in blood pressure or fluid retention. Similarly, it is also possible that the lesser hydrochlorothiazide bioavailability could lead to increased serum potassium levels. However, extensive clinical experience with 'Dyazide' suggests that these conditions have not been commonly observed in clinical practice. Angiotensin-converting enzyme (ACE) inhibitors can elevate serum potassium; use with caution with 'Dyazide'. Do periodic serum electrolyte determinations (particularly important in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with amphotericin B or corticosteroids or corticotropin[ACTH]). Periodic BUN and serum creatinine determinations should be made, especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency. Cumulative effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide; dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in cirrhotics with splenomegaly. Antihypertensive effects may be enhanced in post-sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, 'Dyazide' should be used with caution in patients with histories of stone formation. A few occurrences of acute renal failure have been reported in patients on 'Dyazide' when treated with indomethacin. Therefore, caution is advised in administering nonsteroidal anti-inflammatory agents with 'Dyazide'. The following may occur: transient elevated BUN or creatinine or both, hyperglycemia and glycosuria (diabetic insulin requirements may be altered), hyperuricemia and gout, digitalis intoxication (in hypokalemia), decreasing alkali reserve with possible metabolic acidosis. 'Dyazide' interferes with fluorescent measurement of quinidine. Hypokalemia is uncommon with 'Dyazide', but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and 'Dyazide' should laboratory values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. 'Dyazide' should be withdrawn before conducting tests for parathyroid function. Thiazides may add to or potentiate the action of other antihypertensive drugs. Diuretics reduce renal clearance of lithium and increase the risk of lithium toxicity.*

Adverse Reactions: *Muscle cramps, weakness, dizziness, headache, dry mouth, anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions; nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances; postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics). Necrotizing vasculitis, paresthesia, icterus, pancreatitis, xanthopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis, and vertigo have occurred with thiazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitial nephritis have been reported. Impotence has been reported in a few patients on 'Dyazide', although a causal relationship has not been established.*

Supplied: *'Dyazide' is supplied as a red and white capsule, in bottles of 1000 capsules; Single Unit Packages (unit dose) of 100 (intended for institutional use only); in Patient-Pak™ unit-of-use bottles of 100.*

BRS-DZ-L45

a product of
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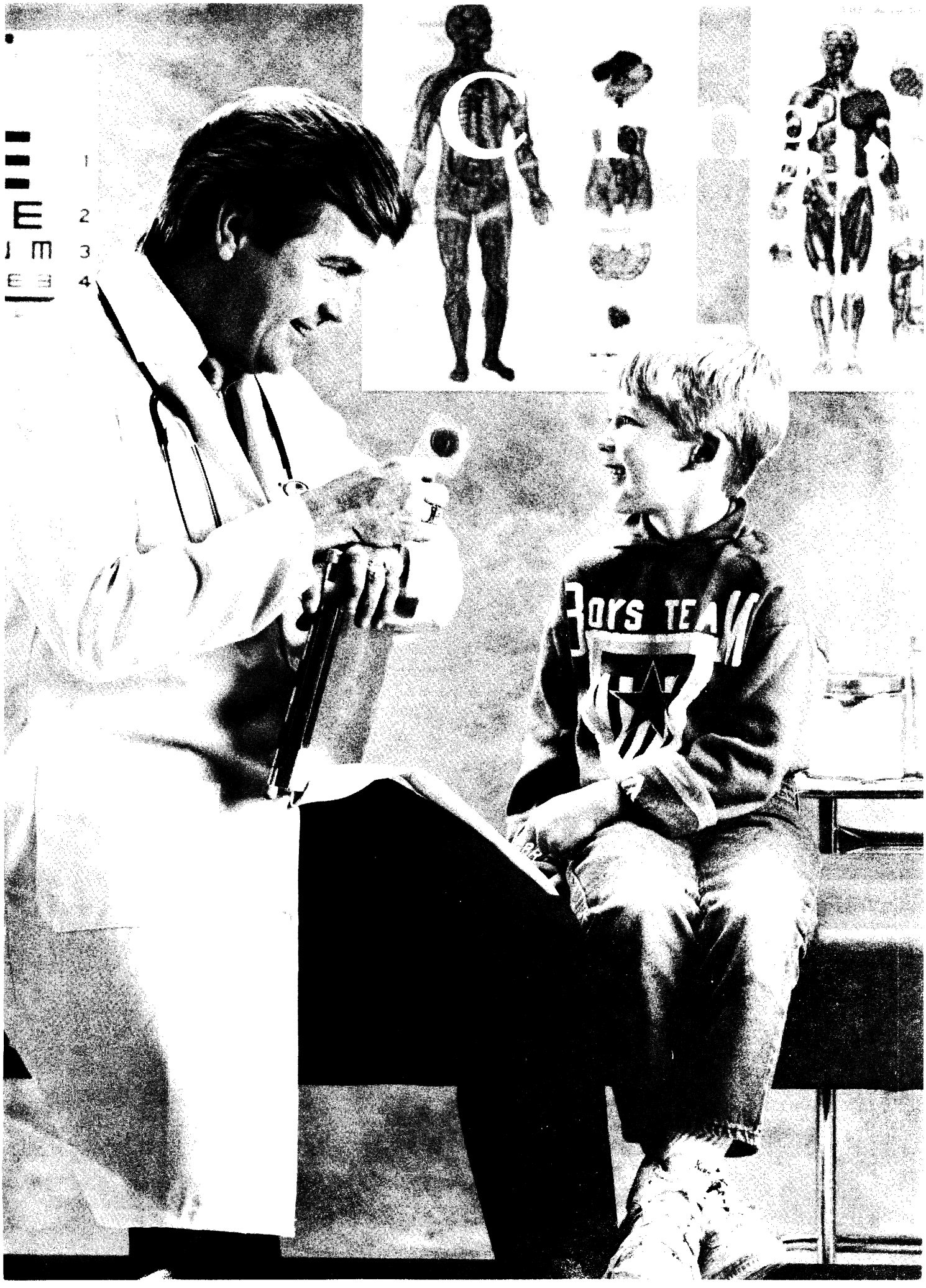
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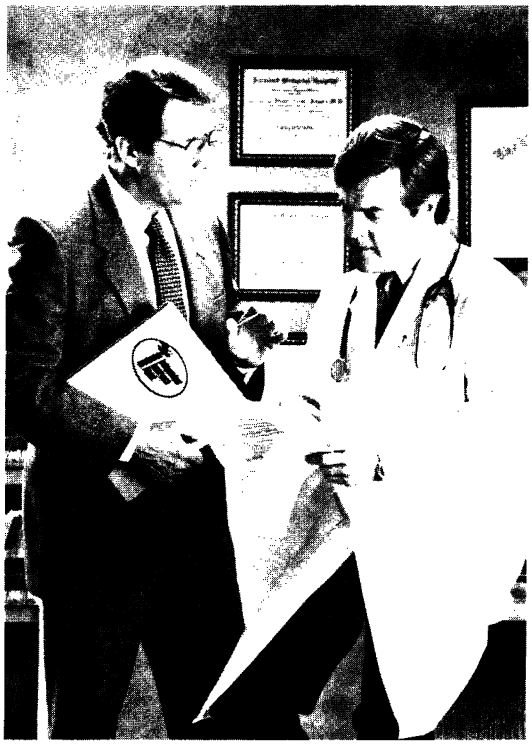

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NEAR STANFORD. Six Internists, all subspecialty trained and members of clinical faculty at Stanford, interested in an Associate with subspecialty interest and training. Should be well grounded in Internal Medicine. Send CV to Dr Bigler, El Camino Internal Medical Group, 125 South Dr, Mountain View, CA 94040.

CRESCENT CITY, CALIFORNIA. Exciting position available at a growing 24,000 visit ER in a rural, coastal community. Fee-for-service with possibility of six figure income. Send CV to Art B. Wong, MD, FACEP, EPMG, 120 Montgomery St, Ste 1825, San Francisco, CA 94104.

FAMILY PRACTICE in four season playground. Live, work, and play in beautiful north Idaho. Excellent professional opportunity. Private practice affiliated with JCAH accredited hospital. For details call Nancy collect at (208) 784-1221, ext 304. Shoshone Medical Center, Jacobs Gulch, Kellogg, ID 83837.

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OB/GYN. Multispecialty group in northwest Washington desires second Obstetrician. Excellent practice opportunity, full range of benefits, early partnership status, all practice costs paid. For more information contact Shane Spray, Administrator, 1400 E. Kincaid, Mount Vernon, WA 98273; (206) 428-2524.

SOUTH CENTRAL WYOMING. Immediate practice opportunity for BC/BE Urologist. Well-equipped JCAH hospital for a service area of approximately 20,000 population. No state or city income tax. Relocation incentives. Superior hunting, fishing, camping, snowmobiling. Three hours to Colorado ski area, five hours to Jackson Hole. One and one-half hours to the mountains. If interested, please send CV and references to D. Abels, DO, Chairman, Recruiting Committee or Richard Mills, Executive Director, Memorial Hospital of Carbon County, Rawlins, WY 82301; (307) 324-2221.

PHYSICIANS WANTED

DERMATOLOGIST. Visalia Medical Clinic has an opening for a BC/BE Dermatologist now staffed by one physician who has been with the Clinic for 15 years. Located in the San Joaquin Valley in central California and population approximately 350,000. Progressive city of 62,000, near national parks and the ocean. Compensation is incentive oriented with advancement to full partnership after one year. Excellent fringe benefits. If interested, CV to John G. Heinsohn, Administrator, 5400 W. Hillsdale, Visalia, CA 93291; (209) 733-5222.

PHYSICIANS WANTED. A General Surgeon and an Oncologist to join 16 physician multispecialty group with attached 40-bed hospital located in southern Idaho. Contact Business Administrator, Box 1233, Twin Falls, ID 83301.

GENERAL PRACTICE. Busy medical center needs full-time physicians for urgent appointments. Significant evening and weekend hours. Abundant free time with no on-call responsibility. Excellent benefits and retirement program. Kaiser Permanente, Santa Teresa Hospital, 250 Hospital Pkwy, San Jose, CA 95119; (408) 972-6180.

FAMILY PRACTICE/GENERAL PRACTICE wanted for full-time practice to work three days a week and share with another Practitioner. Rural setting, good pay, nice people. Can commute for two nights a week, one hour Sacramento, one hour and 15 minutes Nevada City, two hours San Francisco. Contact Charles Rath, MD, 199 E. Webster St, Colusa, CA 95932; (916) 458-7739.

ONCOLOGIST/INTERNIST BC/BE wanted to join hospital-based multispecialty clinic near San Francisco. Complete benefit package. Send résumé to Gary Hillman, MD, Chief, Department of Medicine, Permanente Medical Group, 1150 Veterans Blvd, Redwood City, CA 94063; or call (415) 780-2626.

GENERAL SURGEON. Opportunity for BC/BE Surgeon with fellowship or experience in Vascular Surgery to join Surgeon in active practice in southeastern Washington state; well-equipped 71-bed hospital undergoing expansion. Send current CV to J. Griffith, PO Box 6128, Kennewick, WA 99336.

PHYSICIANS WANTED

OPENINGS for one or two General and one Vascular Surgeon in 175 physician, multispecialty group. Offices adjacent to modern 230-bed hospital in suburbs of south San Jose near excellent recreational facilities. Competitive salary, generous fringe benefits including paid educational leave, vacation, insurance, and retirement. Contact Latimer H. Booth, MD, Chief, Department of Surgery, The Permanente Medical Group, Inc, 260 International Cir, San Jose, CA 95119.

PHYSICIAN OPENING. Ambulatory care/minor emergency center. Full/part-time for Family Practice/Internal Medicine/Emergency Medicine trained, experienced physician located in Tacoma area. Flexible scheduling, pleasant setting, quality medicine. Contact David R. Kennel, MD, 5900 100th St Southwest, Ste 31, Tacoma, WA 98499; (206) 584-3023 or 582-2542.

WASHINGTON. Excellent opportunity for caring BC/BE physician to join a 35 member multispecialty clinic as the second physician in our expanding facility based Immediate Care Department. Competitive salary and generous fringe benefits including paid education leave, vacation, insurance, and retirement. Send inquiries and CV to R. G. Caudill, MD, Walla Walla Clinic, 55 W. Tietan, Walla Walla, WA 99362.

PHYSICIANS WANTED. We have full and part-time locum tenens opportunities available with guaranteed incomes and paid malpractice. For more information, contact John Smith, Locum Tenens, Inc (A Division of Jackson and Coker), 400 Perimeter Center Terrace, Ste 760 WJM, Atlanta, GA 30346; 1 (800) 544-1987.

GENERAL INTERNIST needed for large hospital-based multispecialty clinic. University associated residency program. Attractive salary and complete benefit package. Pleasant setting. BC/BE. California license required. Contact Dennis L. Ostrem, MD, Chief Internal Medicine, The Permanente Medical Group, Inc, PO Box 254999, Sacramento, CA 95865-4999 or call (916) 973-5781. An Equal Opportunity Employer.

FAMILY PRACTITIONER. Busy four physician Family Practice group (including OB) seeks replacement for partner departing fall, 1988. Located in Alaska's capital city in the Tongass National Forest offering year 'round recreation including skiing, boating, and hiking. Guaranteed salary with excellent fringe benefits and opportunity for partnership within one year. Send CV to Sarah A. Isto, MD, Valley Medical Care, Inc, 9309 Glacier Hwy, B-301, Juneau, AK 99801; (907) 789-3181.

PEDIATRICIAN, BE/BC, needed July 1988 in four-season playground. Excellent practice opportunity with positive financial success. Send CV to Dr Gerald E. Carlson, Women's Medical Clinic, 1203 10th St South, Nampa, ID 83651; (208) 467-2400.

OB/GYN, SEATTLE AREA. Rapidly growing practice seeks third OB/GYN. Come practice in a picturesque community on Puget Sound. Nearby mountains and lakes provide limitless recreational opportunities. University of Washington continuing education minutes away. For excellent incentive-oriented compensation and benefits contact Philip DuBois, MD, 7935 216th St SW, Ste E, Edmonds, WA 98020; (206) 775-0681.

ENJOY COUNTRY LIVING and outstanding year 'round outdoor recreation, excellent school system, clean environment! Join two BC Internists with growing practice in historical Wyoming community. We seek BE/BC Internist candidates recently trained or in university affiliated program. Income guarantee, paid malpractice and health insurance, more! Contact Cynthia Lacro, PRO-SEARCH, 305 NE 102nd Ave, Portland, OR 97220; 1 (800) 237-6906.

(Continued on Page 125)

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Specialty	Composite* Insurance Companies	CAP/MPT	Savings with CAP/MPT	Composite* Insurance Companies	CAP/MPT	Savings with CAP/MPT
Psychiatry	$ 5,100	$ 2,365	54%	$ 3,789	$ 2,052	46%
Pediatrics	7,357	2,365	68%	6,208	2,052	67%
Urology	18,571	13,735	26%	14,560	11,776	19%
Anesthesiology	19,704	13,735	30%	16,299	11,776	28%
General Surgery	30,841	17,853	42%	22,388	15,306	32%
Plastic Surgery	31,557	17,853	43%	22,961	15,306	33%
Orthopedic Surgery w/Spinal	39,744	21,971	45%	34,184	18,837	45%
Obstetrics/ Gynecology	49,812	21,971	56%	40,220	18,837	53%

* Insurance company composite rates are averages based upon 4/1/88 rates of The Doctors' Company, 6/1/87 rates of MIEC, 1988 rates of Norcal and SCPIE. Details of source data on request. No costs shown here for San Diego or Imperial County. Other surcharges, credits, reductions may apply. All costs based on mature rate (including retroactive coverage).

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(Continued from Page 122)

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PHYSICIAN WANTED. Family Practice Physician to join 16 physician multispecialty group with attached 40-bed hospital located in southern Idaho. Contact Business Administrator, Box 1233, Twin Falls, ID 83301.

ENT PHYSICIAN, CALIFORNIA. BE/BC ENT to join staff of 14 physician multispecialty group located in the central San Joaquin Valley. Competitive starting salary and full benefits. Excellent living and practice environment. Send CV to William R. Winn, MD, Kaweah Medical Group, Inc., 222 West Willow St, Visalia, CA 93291.

WASHINGTON. Openings for career oriented Emergency Physicians, BC/BE in Emergency or Primary medical specialty. In a Seattle metropolitan hospital with 35,000 annual visits. Excellent salary with partnership potential in stable, growing group. Contact Beth Welsh at Valley Medical Center, 400 S. 43rd St, Renton, WA 98055.

PORTLAND, OREGON. Established, rapidly growing practice seeks BE/BC Internist. Multispecialty group active in private and HMO practice with satellite office. Salary and benefits first two years lead to partnership. Send CV to SMC, 10535 NE Glisan St, Portland, OR 97220, Attn: Dick Hamilton; (503) 256-0594.

FAMILY PRACTICE, PUGET SOUND. 23 physician multispecialty group is seeking Family Practitioner. Our facility has in-house lab and x-ray facilities and is conveniently located one block from Level III hospital. Attractive salary and benefits; partnership opportunity. Send CV to Carol Larsen, Acting Director, c/o The Western Clinic, PO Box 5467, Tacoma, WA 98405.

RHEUMATOLOGIST. Immediate opening for BC/BE Rheumatologist with large prepaid group practice in San Francisco bay area. Busy clinical practice with opportunities for teaching and research. University appointment possible. Competitive salary. Generous benefit package. Respond with CV to Joseph Mason, MD, Chief, Department of Medicine, Permanente Medical Group, 260 International Cir, San Jose, CA 95119, or phone (408) 972-6560.

FAMILY PRACTICE PHYSICIAN WANTED. Salt Lake area family practice clinic. Close to skiing and excellent outdoor recreational opportunities. Income guaranteed and excellent benefits. Contact Robert Davis, MD, Director, Family Medical Center, 1781 West 9000 South, West Jordan, UT 84088; (801) 562-9100.

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Primary Care Physicians needed to work as *locum tenens* in northern California. Radiologists needed statewide. High salary, paid malpractice. Work whenever you like. Permanent placements as well.

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SACRAMENTO. BC/BE Family Physicians needed for full-time primary care clinic, part-time ER/part-time primary care clinic, or full-time in our ER. We are a large-staff model HMO offering competitive salary, excellent benefit package, and shareholder status. California license required. Contact Richard Fury, MD, 1001 Riverside Ave, Roseville, CA 95678 or call (916) 784-4620. EOE.

ASSOCIATE MEDICAL DIRECTOR. Excellent opportunity for BC physicians to become a part of the Medical Department of one of the largest utilization and case management corporations in the U.S. The company specializes in remote utilization review, and in managed medical care for corporate and insurance carrier clients coast-to-coast. There will be an opportunity to work with physicians and develop treatment plans and alternate treatment sites for patients on a nationwide basis. Opportunities for input into corporate programs and strategic planning also exist. Utilization review experience is preferred but not necessary. Specialty Board certification is required. Respond to Director, Medical Department, 3200 S. Highland Ave, Downers Grove, IL 60515-1223.

SAN FRANCISCO. Outstanding opportunity for BC/BE Internist, Family Practitioner, OB/GYN, or Orthopedic Surgeon at 260-bed community hospital in the dynamic South of Market area. Excellent opportunity to join busy, growing practices. Competitive salary and benefits package. Send CV to Walter Kopp, St. Luke's Hospital, 3555 Army St, San Francisco, CA 94110; (415) 641-6543.

ORTHOPEDIST, NEUROLOGIST, AND PHYSIATRIST one to two days per week for office-based practice specializing in evaluation and non-emergency treatment of traumatic injury patients. California license required. Medico-legal experience helpful. Fee for service, with high earning potential. CV to Director, PO Box 14046, San Francisco, CA 94114.

MONTANA. BC Family Practitioner seeks partner with interests in Obstetrics and Rural Medicine to join busy practice in southeast Montana. Office on hospital/NH campus. First year income guarantee, relocation assistance, and other benefits. Enjoy comforts of friendly small community living and recreation that only Montana can offer! Send CV to Cynthia Lacro, PROSEARCH, 305 NE 102nd Ave, Portland, OR 97220; (800) 237-6906.

SURGERY, CALIFORNIA. BE/BC General/Thoracic Surgeon to join staff of 14 physician multispecialty group located in the central San Joaquin Valley. Competitive starting salary and full benefits. Excellent living and practice environment. Send CV to William R. Winn, MD, Kaweah Medical Group, Inc., 222 West Willow St, Visalia, CA 93291.

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INTERNIST. San Francisco-based growing practice BC/BE with or without subspecialty. CV to PO Box 640464, San Francisco, CA 94109.

CALIFORNIA, BERKELEY. Emergency physician group seeking physicians for full-time positions at community hospital-based urgent care center. Applicant must be at least two year post internship. Experience in primary care settings is required. Salary and work conditions are highly competitive. Contact Alta Emergency Medical Group, PO Box 1233, Berkeley, CA 94701.

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PHYSICIANS WANTED IN TEXAS, OKLAHOMA, and ARIZONA. Cardiology, ENT, Family Practice, General Practice, General Surgery, Internal Medicine, OB/GYN, Orthopedic Surgery, Pediatrics, Psychiatry, Radiology. Excellent quality of life, first year guarantee, etc. Other opportunities available also. Reply with CV or call Armando L. Frezza, Medical Support Services, 8806 Balcones Club Dr, Austin, TX 78750; (512) 331-4164.

RESEARCH ASSISTANT/ASSOCIATE PROFESSOR of Medicine to perform research studies, help care for patients in the Diabetes Control and Complications Trial, attend on the Endocrinology Service, and administrate pharmaceutical research studies. Must be BE/BC in Endocrinology and Metabolism or have extensive experience in diabetes research and patient care. Non-tenured position. Filing deadline is August 15, 1988. Contact Dr David Schade, Department of Medicine, University of NM School of Medicine, 2211 Lomas NE, Albuquerque, NM 87131. AA/EOE.

WOMEN'S HEALTH CENTER in Pleasanton, California seeking a Primary Care Physician. Full-time or part-time. Good salary. Lovely community 40 minutes from San Francisco. Contact Bonnie Rathjen, MD, (415) 463-3442.

FAMILY PRACTITIONERS. BE/BC for pre-paid medical group in San Francisco bay area. Send CV to James Conroy, MD, The Permanente Medical Group, Inc, 260 International Cir, San Jose, CA 95119, or call (408) 972-6339.

INTERNIST needed for multispecialty group of 27 physicians in town of 28,000 in agricultural area 20 miles from state capitol. Clinic adjacent to 150-bed hospital. $60,000 guarantee plus bonus first year. Full stockholder status thereafter plus many fringe benefits. Close to excellent outdoor recreational activities. Contact Mike Crane, 215 E Hawaii, Nampa, ID 83651; (208) 467-1121.

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WASHINGTON. Expanding physician-owned emergency group has opening for full-time career-oriented Emergency Physicians in south central Washington. Flexible work schedules, excellent working and living conditions. Send CV to EMP, PC, PO Box 805, Cheyenne, WY 82003; or contact Donald Kougl, MD, (307) 632-1436.

URGENT—FP/GP Physicians needed for excellent solo and group opportunities across the US. For information, call (602) 990-8080; or send CV in confidence to Mitchell & Associates, Inc, PO Box 1804, Scottsdale, AZ 85252.

ORTHOPEDIC SURGEON—BC for Disability Evaluation office. Part- or full-time, regular hours weekdays only, benefits available. Send CV to PO Box 160408, Sacramento, CA 95816.

COTTAGE GROVE, OREGON. Oregon opportunity. Divorced and relocating. Assume $200,000/year Family Practice or be this town's first (and very needed) Pediatrician. Restored fully staffed and equipped office adjacent to grassy park and river. 60-bed hospital with multispecialty coverage. 20 minutes to downtown Eugene, Oregon. Please call Carol King, Business Manager, (503) 942-4413 (daytime).

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Or call (209) 252-3000.

INTERNAL MEDICINE. San Francisco bay area—Immediate opening for BC/BE General Internist in large prepaid group practice. Busy outpatient and hospital practice. Medical house staff program. Opportunity for university appointment, teaching, and clinical research. Competitive salary. Generous fringe benefits including paid educational leave, vacation, insurance, retirement. Respond with CV to Joseph Mason, MD, Chief, Department of Medicine, The Permanente Medical Group, 260 International Cir, San Jose, CA 95119.

BC/BE INTERNIST/FAMILY PRACTITIONER needed for growing dynamic general practice. Guaranteed salary with incentive bonuses. Full partnership available after first year. Excellent family and medical environment. Contact Donald L. Rossman, MD, 1055 W Louise Ave, Manteca, CA 95336; (209) 239-4747.

VENTURA (VENTURA COUNTY). Multispecialty group of 35 physicians has immediate positions available for BC/BE Cardiologist. This growth oriented group is located on the California coast, 60 miles north of Los Angeles. Invasive skills preferred. This is an excellent opportunity to join and grow with a successfully expanding group practice in a city chosen by *Money* magazine as one of the ten most preferred cities to live in the USA. Guaranteed salary plus incentives. Excellent benefits. No investment required. City is a great place to raise a family in a clean environment. Send résumés to Recruitment, Cardiologist, 2705 Loma Vista Rd, Ventura, CA 93003.

GENERAL SURGEON—RARE OPPORTUNITY, BC/BE, to join internationally recognized Hernia Institute academically oriented. Send CV to Irving Lichtenstein, MD, c/o Lichtenstein Hernia Institute, 9201 Sunset Blvd, Ste 505, Los Angeles, CA 90069.

GENERAL INTERNIST OR BC FAMILY PRACTITIONER. Excellent opportunity to start or relocate in growing resort community in need of another physician. Hospital privilege a must. Will help a motivated individual. L. D. Lamothe, MD, 13120 Palm Dr, Desert Hot Springs, CA 92240.

VENTURA (VENTURA COUNTY). Multispecialty group of 35 physicians has immediate positions available for BC/BE General Internists. This growth oriented group is located on the California coast, 60 miles north of Los Angeles. Guaranteed salary plus incentives. Excellent benefits. No investment required. City is a great place to raise a family in a clean environment. Send résumés to Recruitment, Internist, 2705 Loma Vista Rd, Ventura, CA 93003.

SAN DIEGO, CALIFORNIA. Hospital affiliated primary care group seeking additional associates. BC/BE in Family Medicine with minor emergency skills. New state-of-the-art, outpatient primary care centers with excellent compensation package. Send CV to Medical Director, Mercy CarePoint Medical Group, 1011 Camino Del Rio South, #450(4B), San Diego, CA 92108.

FAMILY PRACTICE position available in Berkeley, California. Join two female MDs, two NPs and one PA in a busy, well-established practice. Permanent position to start at mutually agreed upon date in next 18 months. Must do OB. Please write East Bay Family Practice, 2500 Milvia St, Berkeley, CA 94704 or call (415) 540-8200, Edie Silber.

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INTERNIST, BC/BE, California license. Duties will include outpatient, admissions, and in-patient care. Send résumé to Dr Susan J. Steinberg, Medical Director, Access Health Care, 26 California St, San Francisco, CA 94111.

BC/BE CARDIOLOGIST to join three invasive/noninvasive Cardiologists in practice, Portland, Oregon metropolitan area. Send CV to Number 105, Western Journal of Medicine, PO Box 7602, San Francisco, CA 94120-7602.

INDUSTRIAL PHYSICIAN, California central coast. Successful Internal Medicine clinic with immediate opening for full-time MD. No nights or weekends. Internal Medicine experience desirable, Family Practice or Emergency Medicine background acceptable. Paid malpractice. Income competitive based on experience. Growing community of 80,000. Send CV to R. D. Shaw, MD, 1400 E Church St, Santa Maria, CA 93454; (805) 922-5811, ext 196.

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PHYSICIANS needed to perform consultative, independent medical examinations in Washington and Oregon with respected company. Part-time opportunities for Orthopedists, Neurologists, Psychiatrists. Must have current license. Send letter of interest and résumé to 4105 E Madison, Ste 246, Seattle, WA 98112.

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(Continued on Page 130)

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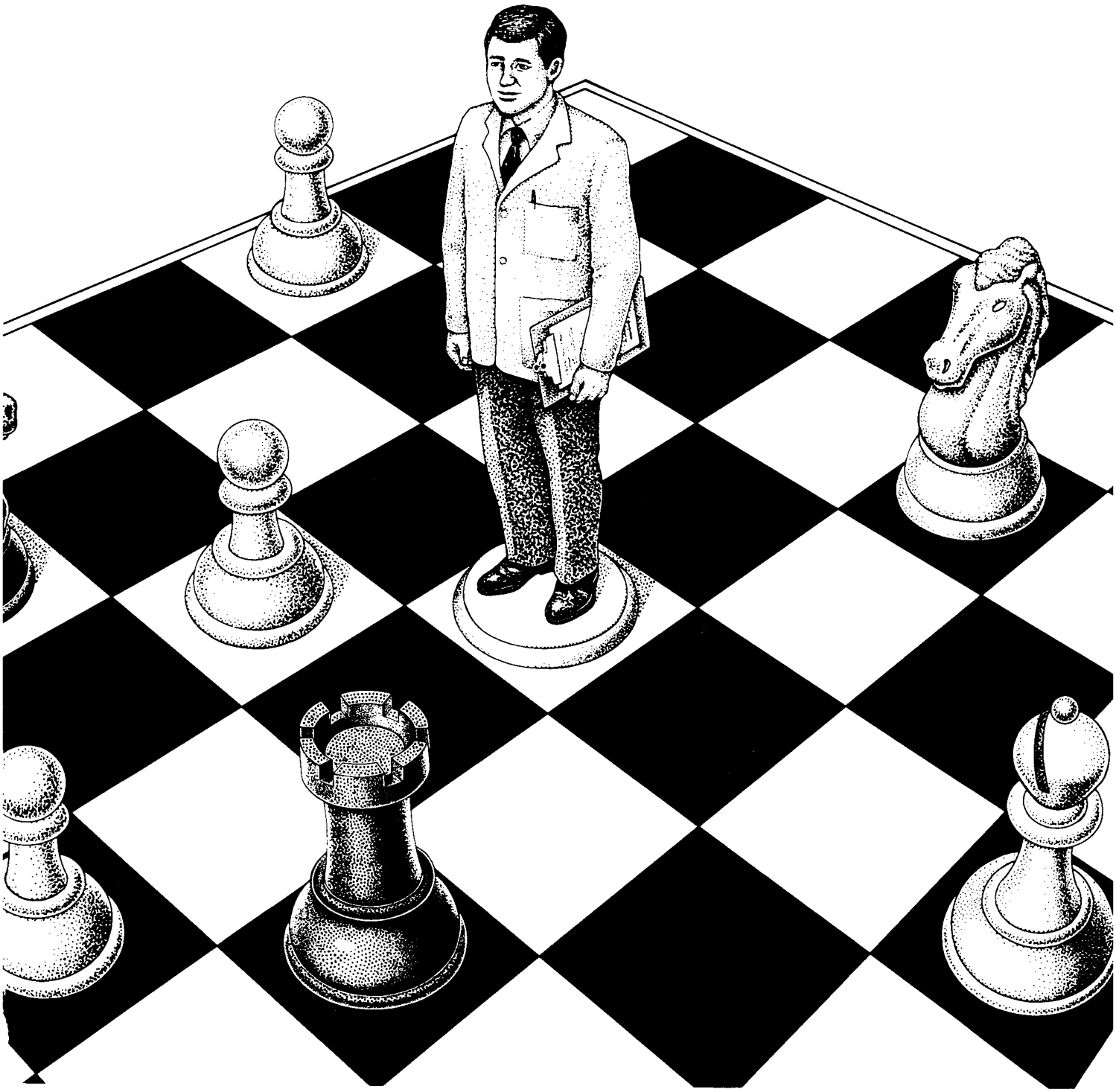

(Continued from Page 127)

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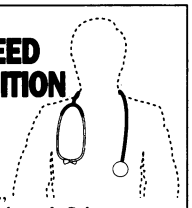

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TRANSLATIONS. Medical, Biological, General. Several European languages into English. Contact William B. Gallagher, MD, 6595 N Oracle Rd, Tucson, AZ 85704; (602) 326-7000 or (602) 298-3489.

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Rocephin® IV·IM

ceftriaxone sodium/Roche

Before prescribing, please consult complete product information, a summary of which follows:

INDICATIONS AND USAGE: Rocephin is indicated for the treatment of the following infections when caused by susceptible organisms:

LOWER RESPIRATORY TRACT INFECTIONS caused by *Strep. pneumoniae, Streptococcus* species (excluding enterococci), *Staph. aureus, H. influenzae, H. parainfluenzae, Klebsiella* species (including *K. pneumoniae*), *E. coli, E. aerogenes, Proteus mirabilis* and *Serratia marcescens*.

SKIN AND SKIN STRUCTURE INFECTIONS caused by *Staph. aureus, Staph. epidermidis, Streptococcus* species (excluding enterococci), *E. cloacae, Klebsiella* species (including *K. pneumoniae*), *Proteus mirabilis* and *Pseudomonas aeruginosa*.

URINARY TRACT INFECTIONS (complicated and uncomplicated) caused by *E. coli, Proteus mirabilis, Proteus vulgaris, M. morganii* and *Klebsiella* species (including *K. pneumoniae*).

UNCOMPLICATED GONORRHEA (cervical/urethral and rectal) caused by *Neisseria gonorrhoeae*, including both penicillinase and nonpenicillinase producing strains.

PELVIC INFLAMMATORY DISEASE caused by *N. gonorrhoeae*.

BACTERIAL SEPTICEMIA caused by *Staph. aureus, Strep. pneumoniae, E. coli, H. influenzae* and *K. pneumoniae*.

BONE AND JOINT INFECTIONS caused by *Staph. aureus, Strep. pneumoniae, Streptococcus* species (excluding enterococci), *E. coli, P. mirabilis, K. pneumoniae* and *Enterobacter* species.

INTRA-ABDOMINAL INFECTIONS caused by *E. coli* and *K. pneumoniae*.

MENINGITIS caused by *H. influenzae, N. meningitidis* and *Strep. pneumoniae*. Ceftriaxone has also been used successfully in a limited number of cases of meningitis and shunt infections caused by *Staph. epidermidis* and *E. coli*.

SURGICAL PROPHYLAXIS. Preoperative administration of a single 1 gm dose may reduce incidence of postoperative infections in patients undergoing surgical procedures classified as contaminated or potentially contaminated (*e.g.*, vaginal or abdominal hysterectomy) and in those for whom infection at the operative site presents serious risk (*e.g.*, during coronary artery bypass surgery).

Although ceftriaxone has been shown to have been as effective as cefazolin in the prevention of infection following coronary artery bypass surgery, no placebo-controlled trials have been conducted to evaluate any cephalosporin antibiotic in the prevention of infection following coronary artery bypass surgery. When administered before indicated surgical procedures, a single 1 gm dose provides protection from most infections due to susceptible organisms for duration of procedure.

SUSCEPTIBILITY TESTING: Before instituting treatment with Rocephin, appropriate specimens should be obtained for isolation of the causative organism and for determination of its susceptibility to the drug. Therapy may be instituted prior to obtaining results of susceptibility testing.

CONTRAINDICATIONS: Rocephin is contraindicated in patients with known allergy to the cephalosporin class of antibiotics.

WARNINGS: BEFORE THERAPY WITH ROCEPHIN IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPHALOSPORINS, PENICILLINS OR OTHER DRUGS. THIS PRODUCT SHOULD BE GIVEN CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS. ANTIBIOTICS SHOULD BE ADMINISTERED WITH CAUTION TO ANY PATIENT WHO HAS DEMONSTRATED SOME FORM OF ALLERGY, PARTICULARLY TO DRUGS. SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE THE USE OF SUBCUTANEOUS EPINEPHRINE AND OTHER EMERGENCY MEASURES.

Pseudomembranous colitis has been reported with the use of cephalosporins (and other broad-spectrum antibiotics); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with antibiotic use.

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis. Cholestyramine and colestipol resins have been shown to bind to the toxin *in vitro*.

Mild cases of colitis respond to drug discontinuance alone. Moderate to severe cases should be managed with fluid, electrolyte and protein supplementation as indicated.

When the colitis is not relieved by drug discontinuance or when it is severe, oral vancomycin is the treatment of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should also be considered.

Rarely, shadows suggesting sludge have been detected by sonograms of the gallbladder in asymptomatic and symptomatic patients. This appears to be reversible on discontinuation of therapy. In a few symptomatic patients receiving higher than usual doses, who underwent surgery, sludge containing traces of ceftriaxone was recovered from surgical specimens. Discontinue therapy in patients who develop signs or symptoms suggestive of gallbladder disease; consider conservative management.

PRECAUTIONS: *GENERAL*: Although transient elevations of BUN and serum creatinine have been observed, at the recommended dosages, the nephrotoxic potential of Rocephin is similar to that of other cephalosporins.

Ceftriaxone is excreted via both biliary and renal excretion (see Clinical Pharmacology). Therefore, patients with renal failure normally require no adjustment in dosage when usual doses of Rocephin are administered, but concentrations of drug in the serum should be monitored periodically. If evidence of accumulation exists, dosage should be decreased accordingly.

Dosage adjustments should not be necessary in patients with hepatic dysfunction; however, in patients with both hepatic dysfunction and significant renal disease, Rocephin dosage should not exceed 2 gm daily without close monitoring of serum concentrations.

Alterations in prothrombin times have occurred rarely in patients treated with Rocephin. Patients with impaired vitamin K synthesis or low vitamin K stores (*e.g.*, chronic hepatic disease and malnutrition) may require monitoring of prothrombin time during Rocephin treatment. Vitamin K administration (10 mg weekly) may be necessary if the prothrombin time is prolonged before or during therapy.

Prolonged use of Rocephin may result in overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Rocephin should be prescribed with caution in individuals with a history of gastrointestinal disease, especially colitis.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: Carcinogenesis: Considering the maximum duration of treatment and the class of the compound, carcinogenicity studies with ceftriaxone in animals have not been performed. The maximum

duration of animal toxicity studies was six months.

Mutagenesis: Genetic toxicology tests included the Ames test, a micronucleus test and a test for chromosomal aberrations in human lymphocytes cultured *in vitro* with ceftriaxone. Ceftriaxone showed no potential for mutagenic activity in these studies.

Impairment of Fertility: Ceftriaxone produced no impairment of fertility when given intravenously to rats at daily doses up to 586 mg/kg/day, approximately 20 times the recommended clinical dose of 2 gm/day.

PREGNANCY. Teratogenic Effects: Pregnancy Category B. Reproductive studies have been performed in mice and rats at doses up to 20 times the usual human dose and have no evidence of embryotoxicity, fetotoxicity or teratogenicity. In primates, no embryotoxicity or teratogenicity was demonstrated at a dose approximately three times the human dose. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nonteratogenic Effects: In rats, in the Segment I (fertility and general reproduction) and Segment III (perinatal and postnatal) studies with intravenously administered ceftriaxone, no adverse effects were noted on various reproductive parameters during gestation and lactation, including postnatal growth, functional behavior and reproductive ability of the offspring, at doses of 586 mg/kg/day or less.

NURSING MOTHERS. Low concentrations of ceftriaxone are excreted in human milk. Caution should be exercised when Rocephin is administered to a nursing woman.

PEDIATRIC USE: Safety and effectiveness of Rocephin in neonates, infants and children have been established for the dosages described in the Dosage and Administration section. *In vitro* studies have shown ceftriaxone, like some other cephalosporins, can displace bilirubin from serum albumin. Exercise caution before administration to hyperbilirubinemic neonates, especially prematures.

ADVERSE REACTIONS: Rocephin is generally well tolerated. In clinical trials, the following adverse reactions, which were considered to be related to Rocephin therapy or of uncertain etiology, were observed.

LOCAL REACTIONS– pain, induration or tenderness at the site of injection (1%). Less frequently reported (less than 1%) was phlebitis after I.V. administration.

HYPERSENSITIVITY – rash (1.7%). Less frequently reported (less than 1%) were pruritus, fever or chills.

HEMATOLOGIC—eosinophilia (6%), thrombocytosis (5.1%) and leukopenia (2.1%). Less frequently reported (less than 1%) were anemia, neutropenia, lymphopenia, thrombocytopenia and prolongation of the prothrombin time.

GASTROINTESTINAL—diarrhea (2.7%). Less frequently reported (less than 1%) were nausea or vomiting, and dysgeusia.

HEPATIC—elevations of SGOT (3.1%) or SGPT (3.3%). Less frequently reported (less than 1%) were elevations of alkaline phosphatase and bilirubin.

RENAL—elevations of the BUN (1.2%). Less frequently reported (less than 1%) were elevations of creatinine and the presence of casts in the urine.

CENTRAL NERVOUS SYSTEM – headache or dizziness were reported occasionally (less than 1%).

GENITOURINARY—moniliasis or vaginitis were reported occasionally (less than 1%).

MISCELLANEOUS—diaphoresis and flushing were reported occasionally (less than 1%).

Other rarely observed adverse reactions (less than 0.1%) include leukocytosis, lymphocytosis, monocytosis, basophilia, a decrease in the prothrombin time, jaundice, gallbladder sludge, glycosuria, hematuria, anaphylaxis, bronchospasm, serum sickness, abdominal pain, colitis, flatulence, dyspepsia, palpitations and epistaxis.

DOSAGE AND ADMINISTRATION: Rocephin may be administered intravenously or intramuscularly. The usual adult daily dose is 1 to 2 gm given once a day (or in equally divided doses twice a day) depending on the type and severity of the infection. The total daily dose should not exceed 4 grams.

For the treatment of serious miscellaneous infections in children, other than meningitis, the recommended total daily dose is 50 to 75 mg/kg (not to exceed 2 grams), given in divided doses every 12 hours.

Generally, Rocephin therapy should be continued for at least two days after the signs and symptoms of infection have disappeared. The usual duration is 4 to 14 days; in complicated infections longer therapy may be required.

In the treatment of meningitis, a daily dose of 100 mg/kg (not to exceed 4 grams), given in divided doses every 12 hours, should be administered with or without a loading dose of 75 mg/kg.

For the treatment of uncomplicated gonococcal infections, a single intramuscular dose of 250 mg is recommended.

For preoperative use (surgical prophylaxis), a single dose of 1 gm administered 1/2 to 2 hours before surgery is recommended.

When treating infections caused by *Streptococcus pyogenes*, therapy should be continued for at least ten days.

No dosage adjustment is necessary for patients with impairment of renal or hepatic function; however, blood levels should be monitored in patients with severe renal impairment (*e.g.*, dialysis patients) and in patients with both renal and hepatic dysfunctions.

HOW SUPPLIED: Rocephin (ceftriaxone sodium/Roche) is supplied as a sterile crystalline powder in glass vials and piggyback bottles. The following packages are available:

Vials containing 250 mg, 500 mg, 1 gm or 2 gm equivalent of ceftriaxone, piggyback bottles containing 1 gm or 2 gm equivalent of ceftriaxone, bulk pharmacy containers containing 10 gm equivalent of ceftriaxone (NOT FOR DIRECT ADMINISTRATION).

Also supplied as a sterile crystalline powder as follows:

ADD-Vantage Vials** containing 1 gm or 2 gm equivalent of ceftriaxone.

Also supplied premixed as a frozen iso-osmotic, sterile, nonpyrogenic solution of ceftriaxone sodium in 50 mL single dose plastic containers,† as follows:

1 gm equivalent of ceftriaxone, iso-osmotic with approximately 1.9 gm dextrose hydrous, USP added.

2 gm equivalent of ceftriaxone, iso-osmotic with approximately 1.2 gm dextrose hydrous, USP added.

NOTE: Rocephin in the frozen state should not be stored above -20°C.

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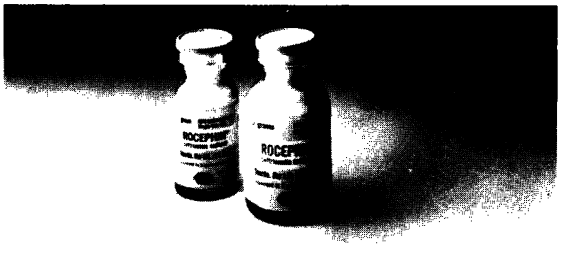

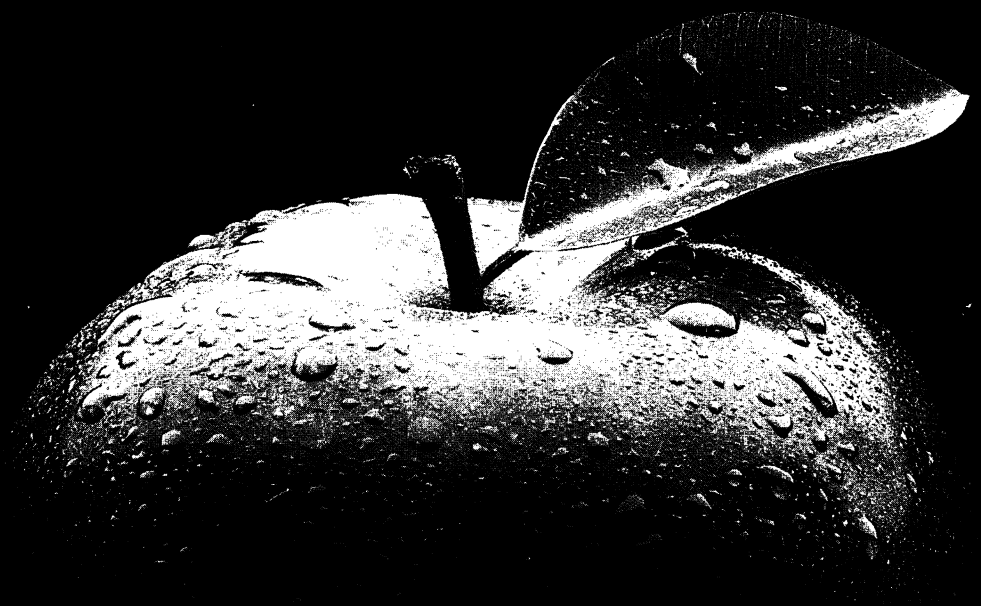

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